ORAL ARGUMENT NOT YET SCHEDULED

Case No. 24-1188

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN WATER WORKS ASSOCIATION, et al.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review

RESPONDENTS' PROOF BRIEF

Dated: December 23, 2024

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RESPONDENTS' CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel for Respondents United States Environmental Protection Agency ("EPA") and EPA Administrator Michael S. Regan submit this certificate as to parties, rulings, and related cases.

A. Parties and Amici

The petitioners, respondents, and intervenors in these consolidated cases are set forth in the brief of American Water Works Association and Association of Metropolitan Water Agencies ("Utility Petitioners") (ECF 2078734, "Utility Br."), and in the brief of National Association of Manufacturers, American Chemistry Council, and the Chemours Company FC, LLC ("Industry Petitioners") (ECF 2078734, "Industry Br.").

In addition to those parties listed in Petitioners' briefs, Chamber of Commerce of the United States of America is participating as Amicus Curiae for Petitioners. Additionally, the State of Connecticut, Cape Fear River Watch, Center for Environmental Health, Harper Peterson, Toxic Free North Carolina, and Michael Watters are participating as Amici Curiae for Respondents. In addition, an unidentified "group of interested scientists" is seeking to participate as Amici Curiae for Respondents. (ECF 2089133).

B. Rulings Under Review

The agency action under review is EPA's rule entitled "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32532 (April 26, 2024).

C. Related Cases

The above-captioned case (No. 24-1188) has been consolidated with two additional petitions for review, *National Ass'n of Manufacturers, et al. v. EPA, et al.* (No. 24-1191) and *The Chemours Co. FC, LLC v. EPA, et al.* (No. 24-1192). Respondents are not aware of any other related cases within the meaning of Circuit Rule 28(a)(1)(C).

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TABLE OF CONTENTS

Respondents' Certificate as to Parties, Rulings, and Related Cases i
Table of Contents iii
Table of Authorities vii
Glossary xiii
Introduction 1
Statement of Jurisdiction 3
Statement of the Issues 3
Pertinent Statutes and Regulations 4
Statement of the Case 4
I. The Safe Drinking Water Act 4
II. The Regulated PFAS 8
A. HFPO-DA 9
1. Health Effects 9
2. Occurrence 9
3. Non-Drinking Water Exposure 10
B. PFNA 11
1. Health Effects 11
2. Occurrence 11
C. Index PFAS Mixtures 12
1. Health Effects 12
2. Occurrence 13
III. EPA's PFAS Drinking Water Regulation 14
A. Regulatory Determinations for PFOA and PFOS 14
B. Science Advisory Board 14
C. Preliminary Regulatory Determinations for Index PFAS and Proposed Goals and Standards for PFOA, PFOS, and Index PFAS 16
D. The Final Rule 18

Summary of Argument 20
Standard of Review.....23
Argument.....24
I. The Regulatory Determinations for the Index PFAS Are Lawful and Followed Proper Procedure. 24
A. EPA Has Authority to Regulate Mixtures of Contaminants. 25
B. The Act Allows EPA to Propose and Finalize a Standard in Parallel with a Regulatory Determination. 29
II. The Record Supports EPA's Determination to Regulate HFPO-DA and PFNA Individually and the Index PFAS Collectively. 38
A. The Record Supports EPA's Occurrence Analyses. 38
1. EPA Properly Considered State Monitoring Data.....41
2. EPA Reasonably Determined There Is a Substantial Likelihood HFPO-DA Will Occur at Frequencies and Levels of Public Health Concern. 45
a. Substantial Evidence Supports EPA's HFPO-DA Occurrence Determination. 45
b. EPA Properly Limited Its Consideration of the Partial UCMR5 Data..... 48
3. EPA Reasonably Determined There Is a Substantial Likelihood PFNA Will Occur at Frequencies and Levels of Public Health Concern. 54
4. EPA Reasonably Determined There Is a Substantial Likelihood Mixtures of the Index PFAS Will Occur at Frequencies and Levels of Public Health Concern. 56
a. EPA Properly Considered Reported Co-Occurrences of Index PFAS. 57
b. EPA Reasonably Statistically Analyzed Index PFAS Co-Occurrence. 58
B. The Record Supports EPA's Determination that the Index PFAS May Have an Adverse Effect on the Health of Persons. 61
III. The Rule's Standards Are Lawful, Reasonable, and Supported by the Record.....65

A. EPA Set the Standards for PFOS and PFOA at the Level That Is as Close to the Goals as Feasible. 66
B. EPA Adequately Considered Alternative Standards. 72
C. EPA Has Authority to Promulgate Standards in the Form of a Hazard Index. 74
D. The Index PFAS Standard Appropriately Regulates Mixtures of Index PFAS. 78
E. The HFPO-DA Individual Standard Is Reasonable and Supported by the Record. 81
1. EPA Reasonably Considered Non-Drinking Water Exposure to HFPO-DA. 81
2. EPA Reasonably Relied on Rodent Studies Showing HFPO-DA Elicits a Constellation of Adverse Liver Effects Relevant to Humans. 84
3. EPA Reasonably Applied Both Subchronic-to-Chronic and Database Uncertainty Factors of 10. 89
F. EPA Satisfied Its Procedural Requirements for Consultation with the Science Advisory Board. 92
IV. EPA Appropriately Considered Costs and Benefits in Promulgating the Rule. 95
A. EPA's Selection of "Feasible" Standards Does Not Depend on Comparison of Costs and Benefits. 95
B. The Act Precludes Judicial Review of EPA's Finding That the Rule's Benefits Justify Its Costs. 99
C. EPA Reasonably Determined that the Rule's Benefits Justify Its Costs. 103
1. To the Extent the Court May Review EPA's Assessment of Costs and Benefits, The Scope Is Limited to Arbitrary-and-Capricious Review. 103
2. EPA Properly Based Its Determination on Both the Quantified and Nonquantifiable Costs and Benefits. 105
3. EPA Was Not Required to Conduct a Stand-Alone Economic Analysis for Each Individual Standard in the Rule. 110
4. EPA Addressed Petitioners' Specific Concerns with the Economic Analysis in the Record. 114

V. None of Petitioners' Arguments Warrant Vacatur of the Entire Rule. 120
Conclusion 122
Certificates of Compliance and Service.....123

TABLE OF AUTHORITIES

CASES

Abbott v. United States,
562 U.S. 8 (2010).....41

Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n,
988 F.2d 146 (D.C. Cir. 1993).....122

Am. Mining Congress v. EPA,
907 F.2d 1179 (D.C. Cir. 1990).....23, 24

Am. Textile Mfrs. Inst. v. Donovan,
452 U.S. 490 (1981).....67

Appalachian Power Co. v. EPA,
251 F.3d 1026 (D.C. Cir. 2001).....107

Bluewater Network v. EPA,
370 F.3d 1 (D.C. Cir. 2004).....39

City of Portland v. EPA,
507 F.3d 706 (D.C. Cir. 2007)..... 66, 67, 74, 96, 98

City of Waukesha v. EPA,
320 F.3d 228 (D.C. Cir. 2003)..... 23, 36, 37, 76, 94, 113

Coal. for Renewable Nat. Gas v. EPA,
108 F.4th 846 (D.C. Cir. 2024).....39, 41

Consol. Edison Co. of New York, Inc. v. FERC,
347 F.3d 964 (D.C. Cir. 2003).....65

Corley v. United States,
556 U.S. 303 (2009).....26

Del. Dep't Nat. Res. & Env't Control v. EPA,
895 F.3d 90 (D.C. Cir. 2018).....26

Duncan v. Walker,
533 U.S. 167 (2001).....26

Fed. Trade Comm'n v. Morton Salt Co.,
334 U.S. 37 (1948).....61

Huntsman Petrochemical LLC v. EPA,
114 F.4th 727 (D.C. Cir. 2024).....23, 88

Int'l Fabricare Inst. v. EPA,
972 F.2d 384 (D.C. Cir. 1992)..... 23, 67, 68, 105

Loper Bright Enters. v. Raimondo,
144 S. Ct. 2244 (2024)..... 24, 25, 28, 39, 74

Michigan v. EPA,
576 U.S. 743 (2015).....104

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983)..... 23, 90, 104, 105

Nat'l Ass'n for Surface Finishing v. EPA,
795 F.3d 1 (D.C. Cir. 2015).....109, 110

NRDC v. EPA,
529 F.3d 1077 (D.C. Cir. 2008).....52, 109

NRDC v. Regan
67 F.4th 397 (D.C. Cir. 2023).....32

NYC C.L.A.S.H., Inc. v. Fudge,
47 F.4th 757 (D.C. Cir. 2022).....82, 85

Sinclar Wyo. Refin. Co. v. EPA,
101 F.4th 871 (D.C. Cir. 2024).....23, 84, 92

U.S. Sugar Corp. v. EPA,
113 F.4th 984 (D.C. Cir. 2024).....23

UARG v. EPA,
573 U.S. 302 (2014).....65

United States v. Am. Trucking Ass'ns,
310 U.S. 534 (1940).....28

West Virginia v. EPA,
597 U.S. 697 (2022).....65

STATUTES

5 U.S.C. § 706.....36

5 U.S.C. § 706(2)(A).....23

42 U.S.C. § 300f(1).....6, 113

42 U.S.C. § 300f(3).....6, 75

42 U.S.C. § 300f(6).....25, 26

42 U.S.C. § 300g-1.....50

42 U.S.C. § 300g-1(a)(3).....6

42 U.S.C. § 300g-1(b)(1).....35, 38, 121

42 U.S.C. § 300g-1(b)(1)(A)-(B).....45

42 U.S.C. § 300g-1(b)(1)(A).....5, 6, 50

42 U.S.C. § 300g-1(b)(1)(A)(i).....61, 63, 64

42 U.S.C. § 300g-1(b)(1)(A)(ii)..... 39, 40, 41, 47, 48

42 U.S.C. § 300g-1(b)(1)(B).....30

42 U.S.C. § 300g-1(b)(1)(B)(i).....5, 35

42 U.S.C. § 300g-1(b)(1)(B)(ii)(I).....5

42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)..... 5, 38, 39, 44, 48, 49, 50, 51

42 U.S.C. § 300g-1(b)(1)(B)(iii).....5, 30, 31, 34

42 U.S.C. § 300g-1(b)(1)(B)(ii)(III).....5, 33, 34, 35

42 U.S.C. § 300g-1(b)(1)(E)..... 14, 29, 30, 32

42 U.S.C. § 300g-1(b)(3)(A).....73, 109

42 U.S.C. § 300g-1(b)(3)(C) 7, 73, 112, 113
42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(II) 114
42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(III) 105, 108, 109
42 U.S.C. § 300g-1(b)(3)(C)(i) 113
42 U.S.C. § 300g-1(b)(3)(C)(i)(I) 110
42 U.S.C. § 300g-1(b)(3)(C)(i)(III) 72
42 U.S.C. § 300g-1(b)(3)(C)(i)(VII) 109
42 U.S.C. § 300g-1(b)(4) 74, 81, 93
42 U.S.C. § 300g-1(b)(4)(A) 6, 74, 104
42 U.S.C. § 300g-1(b)(4)(B) 6, 66, 73, 74, 96, 101
42 U.S.C. § 300g-1(b)(4)(C) 6, 24, 73, 96, 97, 101, 113
42 U.S.C. § 300g-1(b)(4)(D) 66, 67, 69, 96
42 U.S.C. § 300g-1(b)(6) 97, 121
42 U.S.C. § 300g-1(b)(6)(A) 7, 97, 100, 101
42 U.S.C. § 300g-1(b)(6)(D) 24, 100, 103
42 U.S.C. § 300g-1(b)(7) 6
42 U.S.C. § 300g-1(d) 6
42 U.S.C. § 300g-1(e) 92, 95
42 U.S.C. § 300i(a) 27
42 U.S.C. § 300j-4(g) 5, 44, 48, 49
42 U.S.C. § 300j-4(g)(1) 6, 49
42 U.S.C. § 300j-4(g)(3) 5
42 U.S.C. § 300j-4(g)(5) 49

42 U.S.C. § 300j-4(g)(7)(A)-(B) 52
42 U.S.C. § 300j-7 100
42 U.S.C. § 300j-7(a) 32
42 U.S.C. § 300j-7(a)(1) 3
42 U.S.C. § 4365(a) 93
Pub. L. No. 115-270 § 2021 (2018), 132 Stat 3765 52

CODE OF FEDERAL REGULATIONS

40 C.F.R. § 141.23 78
40 C.F.R. § 141.24 78
40 C.F.R. § 141.26 78
40 C.F.R. § 141.64(b) 77
40 C.F.R. § 141.66 77
40 C.F.R. § 141.66(b) 76
40 C.F.R. § 141.66(c) 76
40 C.F.R. § 141.66(d) 76
40 C.F.R. § 141.133 78

FEDERAL REGISTER

44 Fed. Reg. 68624 (Nov. 29, 1979) 29
51 Fed. Reg. 34836 (Sept. 30, 1986) 76
56 Fed. Reg. 3526 (Jan. 30, 1991) 29
63 Fed. Reg. 69390 (Dec. 16, 1998) 29
65 Fed. Reg. 76708 (Dec. 7, 2000) 29, 77
66 Fed. Reg. 45676 (Aug. 29, 2001) 93

67 Fed. Reg. 38222 (June 3, 2002) 45

68 Fed. Reg. 42898 (July 18, 2003).....45

71 Fed. Reg. 388 (Jan. 4, 2006) 29

74 Fed. Reg. 51850 (Oct. 8, 2009).....14

77 Fed. Reg. 26072 (May 2, 2012) 29

78 Fed. Reg. 10270 (Feb. 13, 2013) 93

85 Fed. Reg. 14098 (Mar. 10, 2020).....14

86 Fed. Reg. 4198 (Jan. 15, 2021) 93

86 Fed. Reg. 12272 (Mar. 3, 2021).....14

LEGISLATIVE HISTORY

H.R. Rep. No. 93-1185 (1974),
|*as reprinted in* 1974 U.S.C.C.A.N. 6454.....27, 28, 67

S. Rep. No. 104-169 (1995) 67, 99, 101, 102, 104

H.R. Rep. No. 104-632 (1996).....99

OTHER AUTHORITIES

RANDOM HOUSE COLLEGE DICTIONARY
(Laurence Urdang et al. eds., 1973).....25, 75, 80

GLOSSARY

Board	Science Advisory Board
EPA	U.S. Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HFPO-DA	Hexafluoropropylene oxide dimer acid
Index PFAS	HFPO-DA, PFBS, PFHxS, and PFNA
PFAS	Per- and Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonic Acid
Standard	Maximum Contaminant Level
SDWA	Safe Drinking Water Act
UCMR	Unregulated Contaminant Monitoring Rule

INTRODUCTION

In the rule challenged here, the U.S. Environmental Protection Agency ("EPA") took action to safeguard the nation's drinking water from a class of chemicals so long-lived and persistent in the environment that they are colloquially known as "forever chemicals." Many of these chemicals, known as per- and polyfluoroalkyl substances ("PFAS"), are known to be dangerous to humans (including children and fetuses); do not break down to become less dangerous over human lifespans; and have widely contaminated the nation's drinking water supplies. EPA's action here under the Safe Drinking Water Act ("SDWA" or "Act") provides much-needed protection from the public health risks of these chemicals.

PFAS persist and accumulate in the environment, meaning that once released, they will remain for decades or even millennia. A large and robust body of scientific evidence indicates PFAS exposure can result in cancer and a broad range of other adverse health effects, including developmental, cardiovascular, liver, kidney, immune, endocrine, metabolic, reproductive, and musculoskeletal effects. Many PFAS have been shown to have the same or similar dose-additive health effects, such that exposure to multiple PFAS together compounds the risk presented. And the best available data demonstrates that these chemicals are

present in many geographically dispersed public water systems at levels of public health concern.

To address the associated public health risks, in this rulemaking EPA has promulgated drinking water standards under the Act applicable to six PFAS.[1] JA-[FR_EPA-HQ-OW-2022-0114-3076_32532] (the "Rule"). The Rule culminates a coordinated years-long research and regulatory process across multiple administrations. It establishes enforceable standards that are estimated to prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses. And the Rule does so at a cost that is lower than its quantified benefits, even before accounting for its substantial nonquantifiable health benefits. JA-[FR_32708].

Petitioners' arguments challenging the Rule lack merit.[2] In many of their arguments, Petitioners advance interpretations of EPA's statutory authority or the role of costs in the Act's regulatory process that are inconsistent with the statute and with this Court's precedent. In others, Petitioners second-guess EPA's

[1] The Rule applies to six PFAS: perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), perfluorononanoic acid ("PFNA"), hexafluoropropylene oxide dimer acid ("HFPO-DA," commonly known as GenX Chemicals), and perfluorobutane sulfonic acid ("PFBS"). JA-[FR_32532].

[2] Petitioners in case number 24-1188 ("Utility Petitioners") filed one brief, while Petitioners in case numbers 24-1191 and 24-1192 ("Industry Petitioners") filed a separate brief.

conclusions on scientific issues while misinterpreting or entirely ignoring relevant evidence and explanation in the record. And in still others, Petitioners misstate EPA's past practices under the Act. For all the reasons discussed below, the Court should reject Petitioners' arguments and deny the petitions for review.

STATEMENT OF JURISDICTION

This Court has jurisdiction over the petitions for review under 42 U.S.C. § 300j-7(a)(1).

STATEMENT OF THE ISSUES

1. Whether the Rule's regulatory determinations for PFHxS, PFNA, HFPO-DA, and PFBS (together, the "Index PFAS") are permissible exercises of EPA's statutory authority for which EPA followed the required procedure.
2. Whether the Rule's determinations to regulate the Index PFAS, individually and collectively, are reasonable where:
    a. EPA considered the best available information on occurrence of these contaminants; and
    b. EPA supported its findings on the adverse health effects of mixtures of Index PFAS based on the best available, peer-reviewed science.
3. Whether the Rule's national primary drinking water regulations are reasonable where:

a. EPA addressed Petitioners' comments regarding feasibility of the PFOS and PFOA standards and adequately considered alternatives;

b. EPA regulated mixtures of Index PFAS through a hazard index that meets SDWA's definition of a "maximum contaminant level" and appropriately addresses those contaminants' dose-additive effects;

c. EPA adequately supported its determination of the safe drinking water level of the Index PFAS collectively and HFPO-DA individually; and

d. EPA consulted with its Science Advisory Board on the scientific questions most critical to EPA's proposed Rule.

4. Whether the Court may review EPA's analysis of the Rule's costs and benefits and, if so, whether EPA's determination that the Rule's benefits justify its costs was reasonable.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations not provided in the addendum to Utility Petitioners' Opening Brief are provided in the addendum accompanying this brief.

STATEMENT OF THE CASE

I. The Safe Drinking Water Act

The Safe Drinking Water Act authorizes EPA to promulgate national primary drinking water regulations, which specify enforceable standards limiting contaminants in public water systems.

SDWA provides two processes by which EPA can determine to regulate new contaminants. First, the Act requires EPA to maintain and periodically update a list of contaminants that are candidates for regulation. *Id.* § 300g-1(b)(1)(B)(i). Every five years, EPA must make a determination of whether or not to regulate at least five contaminants on this list. *Id.* § 300g-1(b)(1)(B)(ii)(I). Second, EPA may also make a regulatory determination at any time outside of the candidate listing process. *Id.* § 300g-1(b)(ii)(III). For either approach, EPA must publish a preliminary determination and provide an opportunity for public comment before making its determination. *Id.* § 300g-1(b)(1)(B)(ii)(I), (b)(1)(B)(iii).

EPA determines to regulate a contaminant if three criteria are satisfied:

1. the contaminant may have an adverse effect on the health of persons;
2. the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
3. in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

Id. § 300g-1(b)(1)(A). EPA must make these findings "based on the best available public health information, including the occurrence database established under section 300j-4(g)" of SDWA. *Id.* § 300g-1(b)(1)(B)(ii)(II); *see also id.* § 300j-4(g)(3). The occurrence database consists of "information on the occurrence of

both regulated and unregulated contaminants in public water systems…and reliable information from other public and private sources." *Id*. § 300j-4(g)(1).

For each contaminant EPA decides to regulate, the agency must publish a maximum contaminant level goal ("Goal") and promulgate a national primary drinking water regulation for that contaminant through notice-and-comment rulemaking. *Id.* § 300g-1(a)(3), (b)(1)(A), (d). The Goals are non-enforceable public health goals and are set at the level of a contaminant in drinking water below which "no known or anticipated adverse effects on the health of persons occur and which allow[] an adequate margin of safety." *Id.* § 300g-1(b)(4)(A). The drinking water regulation is enforceable and typically takes the form of a maximum contaminant level ("Standard") setting the "maximum permissible level of a contaminant in water which is delivered to any user of a public water system."[3] *Id.* § 300f(1), (3). EPA generally must set the Standard "as close to the [Goal] as is feasible." *Id.* § 300g-1(b)(4)(B). The statute defines "feasible" as "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds…are available (taking cost into consideration)." *Id*. § 300g-1(b)(4)(D).

[3] Regulations may also take the form of treatment technique requirements. 42 U.S.C. § 300g-1(b)(7). Because the Rule does not include such requirements, this brief focuses only on "Standards."

At proposal, EPA must publish a determination as to "whether the benefits of the [Standard] justify, or do not justify, the costs." *Id.* § 300g-1(b)(4)(C). To inform this determination, SDWA requires EPA to publish a health risk reduction and cost analysis ("Economic Analysis") along with the proposal setting forth the benefits, costs, and other impacts of the proposed Standards. *Id.* § 300g-1(b)(3)(C). EPA must analyze:

1. quantifiable and nonquantifiable health risk reduction benefits likely to occur from treatment to comply with the Standard;
2. quantifiable and nonquantifiable health risk reduction benefits likely to occur from reductions of co-occurring contaminants attributable solely to compliance with the Standard;
3. quantifiable and nonquantifiable costs likely to occur solely as a result of compliance with the Standard;
4. incremental costs and benefits associated with any alternative Standards EPA considers;
5. the effects of the contaminant on the general population and more sensitive subgroups within the population;
6. any increased health risk that may occur as a result of compliance; and
7. other "relevant factors," including the quality and extent of information, uncertainties in the analysis, and the degree and nature of the risk.

Id. § 300g-1(b)(3)(C).

If EPA determines that the benefits of a Standard set as close to the relevant Goal as feasible "would not justify the costs of complying with the [Standard]," it may (at the Administrator's discretion) adopt a less stringent Standard set at a level

that "maximizes health risk reduction benefits at a cost that is justified by the benefits." *Id*. § 300g-1(b)(6)(A).

II. The Regulated PFAS

PFAS are a large class of chemically and structurally similar synthetic chemicals, exposure to which can result in a number of significant health effects, including heart attacks, strokes, and cancers. JA-[FR_32536]. Exposure to several different PFAS elicit many of the same harmful health effects, including effects on the liver, hormone levels, kidneys, development and growth, and the immune, nervous, and reproductive systems. JA-[FR_32537]. These chemicals are used across a variety of products for their ability to withstand heat and to repel water and stains, and break down extremely slowly in the environment. JA-[FR_32536].

The Rule individually regulates five PFAS—PFOS, PFOA, PFNA, PFHxS, and HFPO-DA—in drinking water. JA-[FR_32533]. Additionally, because these chemicals occur together (*i.e.*, "co-occur") and have the same or similar health effects, their individual effects on certain biological systems can add to each other's health impact (referred to as "dose-additivity"). JA-[FR_32532]. The Rule thus regulates mixtures containing two or more of HFPO-DA, PFNA, PFHxS, and PFBS (collectively, the "Index PFAS"). JA-[FR_32533].

Before issuing the Rule, EPA studied for years the health effects and occurrence of these chemicals in drinking water and in the environment, as well as

technology to remove these chemicals from drinking water. The following summarizes the portion of EPA's extensive research relevant here.

A. HFPO-DA

1. Health Effects

The available scientific HFPO-DA health effects literature demonstrates that exposure elicits adverse health effects on development, the liver and kidney, and the reproductive, immune, and hematological systems. JA-[FR_32544]; JA-[MCLG_EPA-HQ-OW-2022-0114-3078_2-1_to_2-2]. EPA submitted critical components of its analysis of HFPO-DA's health effects for independent peer review three times over six years before setting the Standard; all three panels agreed with EPA's assessments. *See* JA-[HFPO-DA_1st_Peer_Review_USEPA_2018b]; JA-[HFPO-DA_2nd_Peer_Review_EPA-HQ-OW-2022-0114-3618]; JA-[HFPO-DA_TA_EPA-HQ-OW-2022-0114-0102_Appx_D].

2. Occurrence

EPA considered data from 25 state water monitoring programs that monitored for HFPO-DA, and from the Department of Defense and the National Water Information System. JA-[Occurrence_Support_EPA-HQ-OW-2022-0114-3086_205-216]. EPA analyzed the state data both for overall detections and for detections above the health reference level (the concentration below which adverse

health effects are not likely to occur), which EPA has calculated as 10 ng/L for HFPO-DA. JA-[MCLG_2-1]. This data demonstrated that HFPO-DA currently occurs in concentrations above the health reference level in public water systems in five geographically diverse states, and that it is currently detected at lower levels in systems in an additional eight states. JA-[Occurrence_Support_205-216].

HFPO-DA continues to be both produced and used in the United States and is chemically stable and resistant to degradation. JA-[Occurrence_Support_198]; JA-[FR_32557]. EPA thus anticipates that contamination will continue, and may increase, in the future. JA-[FR_32557]. Accordingly, EPA found that there is a substantial likelihood HFPO-DA will occur at frequencies and levels of public health concern. JA-[FR_32557].

3. Non-Drinking Water Exposure

To set a health-protective concentration of HFPO-DA in drinking water, EPA also considered the extent of HFPO-DA exposure that occurs through non-drinking water sources. JA-[MCLG_2-3]. EPA conducted a thorough review of the available scientific studies and data on HFPO-DA exposure from other exposure routes, which demonstrated HFPO-DA's presence in certain foods, soil, sewage sludge, air emissions, rainwater, and indoor dust. JA-[MCLG_A-11_to_A-15]. Because these studies did not allow calculation of the specific amount of HFPO-DA exposure from drinking water versus other media, EPA followed its

standard protocol of attributing 20% of exposure to drinking water and 80% to other sources. JA-[MCLG_2-3, A-15]; JA-[RSC_Guide_EPA-HQ-OW-2022-0114-0882_1-7].

B. PFNA

1. Health Effects

Scientific evidence demonstrates that PFNA exposure, like HFPO-DA exposure, elicits adverse effects on development, reproduction, immune function, and the liver. JA-[FR_32544]; JA-[MCLG_1-7_to_1-10, 2-8].

2. Occurrence

EPA considered a variety of national and state data regarding PFNA in public water systems. JA-[Occurrence_Support_163-93]. EPA analyzed the data both for overall occurrences and for occurrences above the health reference level, which EPA has calculated as 10 ng/L. JA-[MCLG_2-7_to_2-10].

Data from EPA's third cycle of unregulated contaminant monitoring ("UCMR3") reported detections of PFNA at concentrations of 20 ng/L or higher – twice the health reference level. *Id*. Fourteen public water systems across seven states detected PFNA at levels at least twice the health reference level. *Id*.; JA-[FR_32556]. Additionally, data collected from 30 state monitoring programs demonstrate public water systems in 12 states in geographically dispersed areas detected PFNA above the health reference level, and systems in an additional

seven states detected concentrations at lower levels. JA-[Occurrence_Support_180-83]. EPA also considered Department of Defense and National Water Information System testing, which demonstrated, *inter alia*, detections above the health reference level at military bases in South Dakota and Texas. JA-[Occurrence_Support_189-90].

Finally, EPA considered that PFNA is chemically stable and resistant to degradation, making it likely to persist in the environment. JA-[Occurrence_Support_163]. Additionally, although PFNA has largely been phased out of production in the United States, legacy stocks still remain in the United States and may be used in products, and both PFNA and products containing PFNA may to be produced internationally and imported into the United States. JA-[FR_32556]. EPA thus determined that there is a substantial likelihood PFNA will occur at frequencies and levels of public health concern. JA-[FR_32556].

C. Index PFAS Mixtures

1. Health Effects

Scientific evidence demonstrates that exposure to Index PFAS elicit many of the same or similar health effects, including effects on the liver, the kidney, cholesterol, and development, and on the immune, endocrine, and hematologic systems. JA-[FR_32545, 32552]; JA-[MCLG_1-5_to_1-11]; JA-[Framework_EPA-HQ-OW-2022-0114-3088_33-38]. These chemicals are "toxicologically

similar," meaning that they "elicit the same or similar adverse health effects (but with differing potencies for effect(s))...." JA-[MCLG_1-7]. This toxicological similarity means that the chemicals are expected to act "dose-additively." JA-[MCLG_1-7]. This means that "individual PFAS, each at doses that are not anticipated to result in adverse health effects, when combined in a mixture may result in adverse health effects." JA-[MCLG_1-11].

2. Occurrence

EPA analyzed state monitoring data, which demonstrates that two or more Index PFAS occur together at levels above the health reference level in public water systems in at least 21 states. JA-[Occurrence_Support_220-51].

EPA also evaluated state data for co-occurrence using groupwise (comparing PFOA and PFOS with Index PFAS) and pairwise (comparing unique pairs of PFAS) statistical analyses. JA-[Occurrence_Support_220-46]; JA-[FR_32589-596]. The groupwise analysis demonstrated that Index PFAS were more likely to occur when PFOA and/or PFOS were present and also that when Index PFAS were present it was more likely that there would be multiple Index PFAS rather than a single Index PFAS. JA-[Occurrence_Support_240]. The pairwise analysis demonstrated how much more likely one Index PFAS was to occur if a second Index PFAS were present. JA-[Occurrence_Support_242-44]. The odds of detecting one Index PFAS if another was present were between 5.2 and 66.0 times

higher than if the other Index PFAS was not present. JA-[Occurrence_Support_242-44]. EPA thus determined that there is a substantial likelihood the Index PFAS will co-occur at frequencies and levels of public health concern. JA-[FR_32552-53].

III. EPA's PFAS Drinking Water Regulation

A. Regulatory Determinations for PFOA and PFOS

EPA added PFOA and PFOS to its list of candidate contaminants for regulation in 2009. 74 Fed. Reg. 51850 (Oct. 8, 2009). In 2020, EPA published a preliminary determination to regulate these contaminants and solicited public comment. 85 Fed. Reg. 14098 (Mar. 10, 2020). In March 2021, EPA made a final determination to regulate PFOA and PFOS, finding that all three statutory criteria were met for each contaminant. 86 Fed. Reg. 12272 (Mar. 3, 2021). This determination triggered a 24-month deadline for EPA to propose Goals and Standards for PFOS and PFOA. 42 U.S.C. § 300g-1(b)(1)(E).

B. Science Advisory Board

Beginning in December 2021, EPA sought review from its Science Advisory Board ("Board") on four draft documents presenting key scientific issues related to its forthcoming proposed Goals and Standards for PFOS, PFOA, and Index PFAS. JA-[SAB_Report_EPA-HQ-OW-2022-0114-3107_1]. These documents included EPA's proposed framework for estimating noncancer health risks associated with

mixtures of PFAS. JA-[Peer_Review_Draft_Mixture_Framework_EPA-HQ-OW-2022-0114-3619].

With respect to PFAS mixtures, EPA asked the Board for feedback on PFAS dose-additivity. EPA provided an in-depth overview of the scientific literature regarding dose-additivity generally and of PFAS specifically. JA-[Peer_Review_Draft_Mixture_Framework_at_16-26]. EPA sought the Board's input on a tiered process for evaluating PFAS mixtures' health risks whereby PFAS mixtures would first be evaluated using one of several approaches, including a hazard index, and, if risk was indicated, more data-intensive approaches would be followed. JA-[Peer_Review_Draft_Mixture_Framework_at_26-29]. The hazard index approach is "EPA's most commonly used component-based mixture risk assessment method," in which EPA divides the concentration of each contaminant by the contaminant's health reference level, then sums the fractional results and compares that sum to the hazard index health reference level of 1. JA-[Framework_57]; JA-[Occurrence_Support_220].

The Board agreed that many PFAS have common health outcomes and are expected to act dose-additively when present together. JA-[SAB_Report_87, 90]. They noted that PFAS "elicit effects…that have common adverse outcomes in several biological systems (e.g., hepatic, thyroid, lipid synthesis and metabolism, developmental and immune toxicities)." JA-[SAB_Report_87, 90]. The Board

supported EPA's use of a hazard index to evaluate PFAS mixtures, but recommended against the tiered approach. JA-[SAB_Report_91-94].

EPA responded to the Board's recommendations in March 2023 and published a draft framework for public comment along with the proposed Rule. JA-[SAB_Response_EPA-HQ-OW-2022-0114-0043]; JA-[Framework_Public_Comment_Draft_EPA-HQ-OW-2022-0114-0030]. EPA published a finalized framework document along with the final Rule in April 2024. JA-[Framework].

C. Preliminary Regulatory Determinations for Index PFAS and Proposed Goals and Standards for PFOA, PFOS, and Index PFAS

In March 2023, EPA proposed the Rule challenged here. JA-[NPRM_EPA-HQ-OW-2022-0114-0027_18638] ("Proposal"). The Proposal included three primary components: (1) proposed Goals and Standards for PFOA and PFOS; (2) a preliminary determination to regulate the four Index PFAS individually and as a mixture; and (3) a proposed Goal and Standard applicable to the Index PFAS individually and as a mixture. *Id.*

First, for PFOA and PFOS, EPA found that these contaminants are likely human carcinogens and (consistent with its historic practice for such contaminants) proposed to set their Goals at zero. [NPRM_18660, 18663]. EPA proposed to set the Standards at 4.0 ng/L, the lowest concentration at which these contaminants can be reliably quantified, known as the practical-quantitation level.

[NPRM_18666]. EPA identified numerous treatment technologies that are both available and have reliably demonstrated ability to achieve concentrations below the proposed Standards. [NPRM_18668].

Second, EPA made a preliminary determination to regulate the four Index PFAS individually and collectively as a mixture. [NPRM_18645]. Based on the best available public health information, including the information discussed in Pt.II, *supra*, EPA proposed to find that PFHxS, HFPO-DA, PFNA, and PFBS (individually and together in mixtures) satisfied the Act's criteria for regulation. [NPRM_18645-52].

Third, EPA proposed a Goal and Standard for the Index PFAS. EPA proposed to regulate these contaminants in the form of a hazard index to protect against dose-additive risk from combinations of these PFAS. [NPRM_18664]. To account for differences in toxicity among the four Index PFAS, the hazard index approach weights each mixture component using a chemical-specific "health-based water concentration" reflecting the level that is protective of health effects over a lifetime of exposure.[4] *Id.* Compliance with the hazard index is calculated by dividing each Index PFAS contaminant's measured concentration by its health-based water concentration, then adding the results for the four Index

[4] EPA proposed health-based water concentrations for PFHxS, HFPO-DA, PFNA, and PFBS of 9.0, 10.0, 10.0, and 2,000.0 ng/L, respectively. [NPRM_18641].

PFAS together. *Id.* at 18665. EPA proposed to set the Goal at 1.0 and to set the Standard at the same level because treatment to the level of the Goal is feasible. [NPRM_18665, 18669]. The Proposal defined a mixture as containing "one or more" of the four Index PFAS, and thus would also regulate each Index PFAS individually if it occurred alone above its health-based water concentration. [NPRM_18638-39]. EPA also solicited comment on whether to promulgate stand-alone Goals and Standards for each of the four Index PFAS individually. [NPRM_18730].

D. The Final Rule

After considering extensive public comments, EPA published the final Rule in April 2024. JA-[FR_32532]. For PFOA and PFOS, the Rule retained the Proposal's Goals and Standards of zero and 4.0 ng/L, respectively. JA-[FR_32567, 32577]. For the Index PFAS, EPA finalized its preliminary regulatory determinations for PFHxS, HFPO-DA, and PFNA as individual contaminants. JA-[FR_32563]. EPA deferred a final determination for PFBS to continue evaluating it against the criteria for regulation, particularly whether the occurrence information supports regulation of that contaminant individually. JA-[FR_32552]. However, EPA found that there is a substantial likelihood of PFBS co-occurrence in mixtures with the other three Index PFAS with a frequency and at levels of public health concern. Accordingly, EPA finalized its regulatory

determination for mixtures containing two or more Index PFAS (including PFBS). JA-[FR_32557-58].

EPA largely retained the proposed Goal and Standard for mixtures of Index PFAS, but revised the number of significant digits (*i.e.*, from 1.0 to 1) and corrected an error in the health-based water concentration for PFHxS. JA-[FR_32571-72]. EPA promulgated individual Goals and Standards for PFHxS, HFPO-DA, and PFNA that are equivalent to their health-based water concentrations. JA-[FR_32573].

EPA included a revised Economic Analysis in its final Rule that updated the Economic Analysis from its Proposal. JA-[FR_32633-32719]. EPA developed quantified estimates for a limited set of the Rule's health benefits, including reduced birth weight effects, cardiovascular effects and renal cell carcinoma from PFOS and PFOA exposure, as well as health benefits from co-removal of other contaminants. JA-[FR_32715]. Weighing these quantified benefits against costs of compliance associated with PFOS, PFOA, and PFHxS, EPA found net positive national-level benefits of $760,000 annually. JA-[FR_32708]. Data limitations prevented EPA from quantifying national-level costs of compliance associated with PFNA, HFPO-DA, or PFBS with the same degree of certainty as PFOA, PFOS, and PFHxS. JA-[FR_32713]. But EPA performed a quantitative sensitivity analysis to estimate their cost impact, which indicated that the costs of

treating these contaminants would likely increase the national compliance costs by $82.4 million, or approximately 5 percent of the Rule's overall quantified costs. JA-[FR_32672]. As required by the Act, EPA also considered the many substantial, nonquantifiable health benefits that are expected to result from compliance with the Rule, including reduced health effects from exposure to PFOS, PFOA, Index PFAS, and other PFAS. JA-[FR_32696-702]. Based on all of the information in its Economic Analysis, EPA reaffirmed its determination made in the Proposal that the benefits of the Rule justify the costs. JA-[FR_32716].

SUMMARY OF ARGUMENT

EPA's regulatory determinations for the Index PFAS (individually and as a mixture) are lawful and were issued in accordance with the statute's procedures. The Act authorizes EPA to regulate "contaminants," a broad term that Congress itself has recognized encompasses groups or mixtures of individual substances. Likewise, the Act permits EPA to propose and finalize the Goal and Standard for a contaminant in parallel with the regulatory determination process, rather than waiting for a final determination. EPA's interpretation is the best reading of the Act because it gives effect to all portions of the statutory text and is consistent with Congressional intent.

EPA's regulatory determinations for the Index PFAS are also reasonable and supported by the administrative record. EPA appropriately relied on occurrence data from robust state datasets, the UCMR3 monitoring cycle (where available), and additional national occurrence database information, which together represent the best available public health information on these contaminants. This data demonstrates that there is a substantial likelihood that HFPO-DA and PFNA will occur both individually and collectively with other Index PFAS at frequencies and levels of public health concern. Moreover, EPA was not required to consider partial data submitted in its ongoing fifth cycle of unregulated contaminant monitoring ("UCMR5") or wait for that monitoring effort to be completed before proceeding, and the preliminary data confirmed EPA's findings of occurrence of these chemicals.

Petitioners' various challenges to the Rule's Standards also lack merit. First, as to PFOS and PFOA, EPA demonstrated in the record that its Standards meet the Act's requirement that they be as close to the Goals as feasible, and Petitioners fail to acknowledge EPA's responses to their narrow objections. EPA also provided a reasoned justification for rejecting Petitioners' suggested alternative Standards. Second, with respect to mixtures of Index PFAS, the Act authorizes EPA to adopt a Standard in the form of a hazard index. The hazard index meets the Act's definition of a "maximum contaminant level," and EPA adequately supported its

decision to use this approach to address the dose-additive effects of Index PFAS. Third, with respect to HFPO-DA individually and the Index PFAS collectively, the Court should reject Petitioners' attempt to second-guess EPA's scientific determinations within its expertise. EPA considered and reasonably addressed each of Petitioners' objections to the scientific inputs of the Index PFAS Standard and the HFPO-DA Standard, and EPA's analyses and conclusions are well-supported by the record.

The Court should also reject Petitioners' challenges to EPA's consideration of costs and benefits in the Rule. The Act and this Court's case law clearly provide that EPA's identification of a Standard at the "feasible" level does not depend on a comparison of costs and benefits. Moreover, the Act does not permit judicial review of EPA's determination as to whether the Rule's benefits justify its costs. To the extent judicial review is available here, EPA reasonably considered all of the relevant factors and responded to Petitioners' comments on the analysis of costs and benefits.

Finally, to the extent the Court finds any of Petitioners' arguments has merit, they cannot justify vacatur of the entire Rule. The Rule's provisions for each contaminant are severable, as are EPA's actions at each step of the regulatory process for each contaminant. Petitioners have not articulated any challenge that would invalidate the Rule in its entirety.

STANDARD OF REVIEW

In reviewing EPA's actions under the Act, this Court follows the Administrative Procedure Act's standard of review. *City of Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003). Under that standard, the Court evaluates whether EPA's action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (quoting 5 U.S.C. § 706(2)(A)).

The Court reviews questions of statutory interpretation *de novo*. *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 991 (D.C. Cir. 2024). On all other questions, the Court applies a deferential standard of review that assesses whether the agency "entirely failed to consider an important aspect of the problem," "offered an explanation for its decision that runs counter to the evidence before the agency," or failed to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Huntsman Petrochemical LLC v. EPA*, 114 F.4th 727, 735 (D.C. Cir. 2024) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The Court accords particular deference to EPA's "evaluation of scientific data within its area of expertise." *Id.*; *see also Sinclair Wyo. Refin. Co. v. EPA*, 101 F.4th 871, 883 (D.C. Cir. 2024) (affording particular deference to "matters implicating predictive judgments"); *Am. Mining Congress v. EPA*, 907

F.2d 1179, 1187 (D.C. Cir. 1990) (affording particular deference to "the scientific judgments of the EPA") (internal citation omitted).

The Act contains special language governing judicial review of EPA's determination under Section 300g-1(b)(4)(C) as to whether the benefits of a Standard justify or do not justify its costs. 42 U.S.C. § 300g-1(b)(6)(D). Such determinations are reviewable only "as part of a review of a final national primary drinking water regulation that has been promulgated based on the determination." *Id.* Where such review is available, the scope is limited to arbitrary-and-capricious review. *Id.*

ARGUMENT

I. The Regulatory Determinations for the Index PFAS Are Lawful and Followed Proper Procedure.

Petitioners challenge EPA's regulatory determinations for the Index PFAS (individually and in a mixture) on both legal and procedural grounds, arguing that the Act does not permit regulation of mixtures and that EPA must finalize the regulatory determination for a contaminant *before* proposing a Goal and Standard. Both arguments lack merit. The Act's definition of "contaminant" is broad, and the "best reading" of the statute is that it permits EPA to regulate contaminants in a group or mixture. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024). Likewise, EPA's interpretation permitting concurrent publication of a

preliminary determination and proposed regulation is the only reading that gives effect to all parts of the Act and to Congress's goals.

A. EPA Has Authority to Regulate Mixtures of Contaminants.

EPA's determination to regulate mixtures of the Index PFAS is consistent with its longstanding interpretation of "contaminant" as including mixtures or groups of individual substances. JA-[FR_32571]. Nothing in the Act confines EPA to "regulat[ing] levels of individual contaminants only, not mixtures of them." *Contra* Industry Br. 31. EPA's interpretation of "contaminant" is the best reading "after applying all relevant interpretive tools," *Loper*, 144 S. Ct. at 2266, including review of the term itself, the statutory context, the legislative history, and EPA's consistent use of its authority to regulate contaminants both individually and collectively.

Congress defined "contaminant" broadly to include "*any* physical, chemical, biological, or radiological substance *or matter* in water." 42 U.S.C. § 300f(6) (emphases added). "Matter" is a broad term that encompasses both pure substances and mixtures or groups of those substances. JA-[FR_32542]; *see* RANDOM HOUSE COLLEGE DICTIONARY 825 (Laurence Urdang et al. eds., 1973) (defining "matter" as "the substance *or substances* of which any physical object consists or is composed" or "a particular *kind* of substance") (emphases added). Industry Petitioners' own brief concedes that a mixture by definition is "*matter*

consisting of two or more components." Industry Br. 32 (emphasis added). Thus, the mixture of Index PFAS that EPA determined to regulate in this Rule is "matter" that falls within the Act's definition of "contaminant."

EPA's interpretation is the only interpretation that gives the statutory definition's component terms "substance" and "matter" independent meaning. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (stating courts must "give effect, if possible, to every clause and word of a statute") (cleaned up). Petitioners' cramped interpretation would render part of the statute "superfluous" by reading out the term "matter" entirely. Industry Br. 32. If "matter" truly encompassed only "*singular* chemical substances," *id.* at 32-33, then that term would be redundant because it would add nothing to the definition of "contaminant" not covered by "substance." 42 U.S.C. § 300f(6); *see Del. Dep't Nat. Res. & Env't Control v. EPA*, 895 F.3d 90, 99 (D.C. Cir. 2018) (stating Court "strive[s] to construe statutes 'so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant") (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)).

EPA's interpretation also comports with the rest of the statute, which likewise supports reading "contaminant" to include mixtures or groups of individual substances. JA-[FR_32542]. For example, SDWA's "emergency powers" provision grants EPA residual authority to take action as necessary

wherever it finds that "*a contaminant* which is present in or is likely to enter a public water system or an underground source of drinking water…may present an imminent and substantial endangerment" to health. 42 U.S.C. § 300i(a) (emphasis added). In enacting this provision, Congress intended to provide EPA with "broad administrative authority" that would be construed "so as to give paramount importance to the objective or protection of the public health." H.R. Rep. No. 93-1185, at 35 (1974), *as reprinted in* 1974 U.S.C.C.A.N. 6454, 6487-88. EPA's responses under this authority are often not limited to individual contaminants and must address a mixture, such as a plume of contaminants in groundwater threatening a drinking water intake. Under Petitioners' reading of "contaminant," EPA could not invoke this authority where a mixture or group of substances is endangering public health, so long as no individual substance alone presents such endangerment. By contrast, EPA's reading effectuates Congressional intent by authorizing action under Section 300i wherever a mixture of substances collectively presents imminent and substantial endangerment.

EPA's interpretation also aligns with the Act's legislative history, which demonstrates that since the Act's adoption in 1974, Congress has recognized that EPA may regulate contaminants as groups. *See* JA-[FR_32542]. Noting the tens of thousands of chemical compounds in use, the responsible House Committee acknowledged it would be "impossible for EPA to regulate each of these

contaminants which may be harmful to health on a contaminant-by-contaminant basis." H.R. Rep. No. 93-1185, at 10, 1974 U.S.C.C.A.N. 6454, 6463. As a result, the Committee anticipated that EPA would "establish primary drinking water regulations for some groups of contaminants," while also establishing regulations for individual contaminants within those groups as appropriate. *Id.* at 6463-64. By allowing for regulation of contaminants as groups, Congress gave EPA leeway to "assure that the public health will be protected from currently undiscovered, unidentified or under-researched subgroups or specific contaminants within the group." *Id.* at 6463.

Finally, EPA has consistently used this authority to promulgate Standards that regulate multiple substances collectively. JA-[FR_32543]; *see Loper*, 144 S. Ct. at 2262 ("[I]nterpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute's meaning.") (citing *United States v. Am. Trucking Ass'ns*, 310 U.S. 534, 549 (1940)). For example, EPA has adopted Standards collectively regulating such groups as: disinfection byproducts (with subgroups including total trihalomethanes and haloacetic acids); radionuclides (with subgroups including alpha emitters, beta/photon emitters, and combined radium-226 and -228);

polychlorinated biphenyls; and asbestos.[5] EPA's regulation of mixtures of Index PFAS fits within this longstanding interpretation of the statute.

B. The Act Allows EPA to Propose and Finalize a Standard in Parallel with a Regulatory Determination.

EPA complied with the Act's procedural requirements when it proposed and finalized its regulatory determinations for the Index PFAS concurrently with its Standards and Goals for those contaminants. And even if this Court agrees with Petitioners' contrary interpretation, any error here was harmless, as Petitioners did not suffer any prejudice from EPA's approach.

The Act provides that EPA

> [1] shall propose the [Goal] and [Standard] for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and [2] may publish such proposed regulation *concurrent with the determination to regulate*.

42 U.S.C. § 300g-1(b)(1)(E) (emphasis added). The best reading of this provision is that "determination to regulate" in the second clause refers to EPA's *preliminary* determination, such that EPA may concurrently proceed with a preliminary determination and proposed regulation rather than waiting for a *final* regulatory determination before proposing a Goal and Standard. JA-[FR_32541]. This reading best fits SDWA's text and structure and effectuates Congress's intent to

[5] 44 Fed. Reg. 68624 (Nov. 29, 1979); 56 Fed. Reg. 3526 (Jan. 30, 1991); 63 Fed. Reg. 69390 (Dec. 16, 1998); 65 Fed. Reg. 76708 (Dec. 7, 2000); 71 Fed. Reg. 388 (Jan. 4, 2006).

propel regulation forward where EPA has evidence that a contaminant warrants regulation.

Although the second clause does not explicitly use the phrase "preliminary determination," Congress generally used the term "determination to regulate" or simply "determination" in subparagraph (b)(1)(B) without distinguishing between preliminary and final—even where the text demonstrably refers to a preliminary determination. JA-[RTC_EPA-HQ-OW-2022-0114-3077_3-109]. Most notably, subparagraph (b)(1)(B)(iii)—which requires EPA to provide for public comment on "the determination for a contaminant"—uses the term "determination" despite the fact that it plainly refers to comment on a *preliminary* determination to regulate. *Id.* § 300g-1(b)(1)(B)(iii).

Because Congress was inconsistent in its terminology, the meaning of "determination" in any particular part of the Act must be inferred from the surrounding context. Here, the relevant context of subparagraph (b)(1)(E) supports reading SDWA to permit EPA to propose a contaminant's Goal and Standard concurrently with the *preliminary* determination. Although this reading admittedly results in "determination to regulate" taking a different meaning in the first clause (addressing the *latest* point at which EPA may propose the Goal and Standard) and second clause (addressing the *earliest* point at which EPA may propose them) of this sentence, that result best comports with the Act's structure and goals.

For one, the rest of the text in this clause indicates Congress intended to allow EPA to align the proposed Goal and Standard with the *public comment process* on a preliminary determination. SDWA's use of the term "publish" is informative: it identifies the specific action (publication) that EPA may take "concurrent[ly]" for both the regulatory determination and Standard-setting processes. The only other place in the Act where Congress refers to publication of a regulatory determination is in subparagraph (b)(1)(B)(iii), where it clearly refers to publication of a *preliminary* regulatory determination for public comment. 42 U.S.C. § 300g-1(b)(1)(B)(iii). No provision of SDWA refers to publication of a *final* regulatory determination. Thus, Congress must have meant that EPA may "publish" its proposed regulation at the same time that it "publish[es]" a preliminary determination to regulate.

Moreover, EPA's interpretation is the only one that gives the second clause of this sentence independent meaning. Reading this provision to only allow publication of proposed Goals and Standards alongside a *final* regulatory determination would render it superfluous, because there is nothing else in SDWA or administrative law generally that suggests EPA would otherwise be precluded from doing so. JA-[RTC_3-110]. There is certainly nothing in subparagraph (b)(1)(E)'s deadline provisions implying such a limitation. In particular, SDWA's requirement to propose regulations "not later than 24 months after" a final

regulatory determination simply establishes when EPA's deadline begins to run; it does not suggest that EPA may only propose them after that deadline is triggered. 42 U.S.C. § 300g-1(b)(1)(E); JA-[RTC_3-108]. If Congress had wanted to create an exclusive window defining the start and end date for EPA's proposal of a Goal and Standard, it would have specified that EPA must do so "within" 24 months, as it did for other deadlines in this same section and elsewhere in the Act. JA-[RTC_3-108]; *see* 42 U.S.C. § 300g-1(b)(1)(E) (requiring EPA to promulgate final Goal and Standard "within 18 months after the proposal thereof"); *id.* § 300j-7(a) (requiring petitions for review to be filed "within the 45-day period beginning on the date of the promulgation of the regulation …").

This Court's decision in *NRDC v. Regan* is not to the contrary. Utility Br. 25 (citing 67 F.4th 397 (D.C. Cir. 2023)). The language Petitioners cite from that case only addresses what obligations are triggered once EPA makes a final regulatory determination for a contaminant.[6] *Id.* *NRDC* never addressed (and had no need to address) at what point EPA may first propose the Goal and Standard for a contaminant.

[6] *NRDC* did not hold that EPA "may only issue a proposed regulation '**after** determining the statutory criteria'" are met. *Contra* Utility Br. 25 (citing *NRDC*, 67 F.4th at 399) (emphasis in original). The Court simply observed that EPA *must* promulgate a *final* Goal and Standard after making that determination. *NRDC*, 67 F.4th at 399.

Additionally, EPA's reading of subparagraph (b)(1)(E) best reflects Congress's goal of accelerating the regulatory process for contaminants that present meaningful public health risks, which is the evident purpose of its allowance for "concurrent" processes. SDWA's 1996 amendments eliminated a previous requirement that EPA regulate 25 additional contaminants every three years, replacing it with the current regulatory determination process. This change reflected Congress's desire for EPA to expeditiously address contaminants that truly warrant regulation, without becoming bogged down in arbitrary quotas and procedural requirements. Moreover, Congress included an explicit provision allowing EPA to initiate regulatory determinations whenever necessary for any contaminant outside of the five-year cycle for its candidate contaminant list, recognizing that EPA may need to act expeditiously to address public health concerns between its periodically scheduled reviews. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III); JA-[RTC_3-110]. EPA's reading effectuates Congress's intent by allowing the agency to move forward in a "concurrent" manner on both a regulatory determination and a proposed regulation where appropriate. Petitioners' contrary reading transforms this provision into a limit rather than an authorization and would unnecessarily delay EPA's efforts to address public health threats in drinking water, with no apparent benefit.

Petitioners insist that "determination to regulate" must take the same meaning wherever it appears. Industry Br. 35-36; Utility Br. 22-25. But as noted above, Congress itself demonstrably used the shorthand "determination" in reference to both preliminary and final determinations. *See* 42 U.S.C. § 300g-1(b)(1)(B)(iii). Petitioners do not meaningfully engage with this inconsistency; they simply deny it exists.

In particular, Petitioners assert the phrase "determination" in clause (b)(1)(B)(iii) must mean something other than a determination to regulate. Utility Br. 28. But their alternative reading—that it refers to publication of a "decision to list a contaminant from the List in the Preliminary Determination"—makes no sense. Nothing in the Act suggests that EPA's selection of which candidate contaminants to consider for regulation constitutes a distinct "determination" with its own public comment requirement separate from the preliminary determination to regulate. Moreover, clause (b)(1)(B)(iii) cannot be limited to EPA's selection of contaminants from its candidate list because it refers to any "determination for a contaminant under clause (ii)," which includes determinations for contaminants *not included* on that list. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III).

Petitioners cast SDWA's regulatory process as a set of rigid, stepwise procedures. Utility Br. 6-10, 18-19. But they misstate the statutory requirements: SDWA does not "mandate[] a sequential, six-step process for regulation," Utility

Br. 18; in fact, the statute clearly provides that the first two "steps" that Petitioners describe are not mandatory. While EPA *may* choose to consider a contaminant for regulation through the candidate listing process in subparagraph (b)(1)(B)(i), the Act also permits EPA at any time to "make a determination to regulate a contaminant that does not appear on" the candidate contaminant list, as it did for the Index PFAS here. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(III); *see also* Industry Br. 34 (describing consultation requirements that apply to development of candidate list, not to regulatory determinations). Petitioners' mistakes reflect their fundamental misunderstanding of the Congressional goals—namely, a desire to proceed expeditiously toward regulation of contaminants with public health risks—that support EPA's interpretation.

Petitioners also make much of EPA's supposed break from "decades of prior policy," emphasizing that before this Rule EPA "had **never** issued a proposed regulation before making a [final] Determination to Regulate." Utility Br. 25-26 (emphasis in original). That is true, but EPA has never issued a Goal or Standard for a newly listed contaminant *after* finalizing a determination to regulate either. This Rule is the first time that EPA has promulgated regulations for a new contaminant since enactment of the 1996 amendments creating the regulatory determination process in Section 300g-1(b)(1). Thus, there is no prior rulemaking establishing precedent on this issue from which EPA departs. The agency

statements that Petitioners rely on consist of simplified informational graphics or high-level summaries of the Act's regulatory process that do not purport to represent EPA's definitive interpretation of any sequencing requirement in the relevant statutory language.[7]

To the extent this Court agrees with Petitioners' interpretation of the Act, any procedural violation here was harmless error. Subparagraph (b)(1)(E) governs the *timing* of EPA's proposed regulations for a contaminant, not its *authority* to propose them. To merit relief from this Court, Petitioners must "show prejudice from an agency procedural violation." *City of Waukesha*, 320 F.3d at 246 (citing 5 U.S.C. § 706).

Petitioners have failed to establish any harm they suffered from EPA's decision to propose the Index PFAS Goals and Standards concurrently with the regulatory determination process. At most, Petitioners suggest that they would have benefitted from a longer time to comment on these actions. Utility Br. 31; Industry Br. 37; *see* JA-[NPRM_18638] (providing 60 days for public comment). As an initial matter, Petitioners were not "entitled" to "two 60-day comment periods," or to a comment period of *any* specific length. Utility Br. 31. The Act does not specify how long EPA must provide for public comments on either a

[7] Moreover, none of these sources actually states that a final determination "must precede" a proposed regulation. Utility Br. 26.

preliminary regulatory determination or a proposed Goal or Standard. In any event, Petitioners fail to demonstrate that if EPA had proceeded through a bifurcated rulemaking process, they "would have submitted additional, different comments that could have invalidated the rationale for" any portion of the Rule. *City of Waukesha*, 320 F.3d at 246. Petitioners had adequate time to prepare detailed comments with supporting studies addressing all aspects of the Rule, including the regulatory determinations, the proposed Goals and Standards for all of the regulated PFAS, and EPA's Economic Analysis.

If anything, EPA's decision to concurrently publish its preliminary regulatory determinations and its proposed regulations for the Index PFAS *promoted* meaningful public comment on those actions by providing Petitioners with much more information to evaluate them. JA-[RTC_3-110]. As a result of this approach, EPA was required to simultaneously publish its Economic Analysis and other record materials supporting the proposed Goals and Standards, including information on risk, cost, occurrence, and benefits that otherwise would not have been available as part of the record for the regulatory determinations. *Id.* Indeed, in this litigation Petitioners are relying on record materials developed for the Goals and Standards to support their challenges to the regulatory determinations. *See* Industry Br. 40.

Accordingly, the Court should reject Petitioners' procedural challenge to the Rule.

II. The Record Supports EPA's Determination to Regulate HFPO-DA and PFNA Individually and the Index PFAS Collectively.

EPA may regulate drinking water contaminants if it determines (1) "there is a substantial *likelihood* that the contaminant *will* occur in public water systems with a frequency and at levels of public health concern" either now or in the future; (2) "the contaminant *may* have an adverse effect on the health of persons;" and (3) "in the sole judgment of [EPA], regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." 42 U.S.C. § 300g-1(b)(1)(A) (emphases added). In keeping with the health protective nature of the Act, these first two criteria are not onerous. Moreover, in all of these determinations, EPA is to use "the best *available* public health information," underscoring the importance of EPA acting expeditiously to protect human health. *Id*. § 300g-1(b)(1)(B)(ii)(II) (emphasis added).

Here, EPA considered extensive scientific literature, water monitoring data, and statistical analyses to determine to regulate HFPO-DA and PFNA individually, as well as the Index PFAS as a group.

A. The Record Supports EPA's Occurrence Analyses.

EPA used the "best available" data, both national and state, when determining that "there is a substantial likelihood" that PFNA and HFPO-DA

individually[8] and all Index PFAS collectively "will occur in public water systems at a frequency and at levels of public health concern." 42 U.S.C. § 300g-1(b)(1)(A)(ii), (B)(ii)(II); JA-[Occurrence_Support_160-258]. The statute mandates only two criteria to find sufficient current or substantially likely future occurrence: (1) a "frequency...of public health concern" and (2) "levels of public health concern." 42 U.S.C. § 300g-1(b)(1)(A)(ii). The statute has no geographic mandate. Thus, the "best" reading of the "plain text" of the statute is that EPA has discretion to regulate a contaminant anywhere in the United States if the contaminant either does or likely will occur at both frequencies and levels of public health concern. *Loper*, 144 S. Ct. at 2266; *Coal. for Renewable Nat. Gas v. EPA*,108 F.4th 846, 852-53 (D.C. Cir. 2024).

Guided by this standard, EPA fully explained "how it arrived at" its assessments of public health concern by providing "a reasonable explanation of the specific analysis and evidence upon which the Agency relied...." *Bluewater Network v. EPA*, 370 F.3d 1, 21 (D.C. Cir. 2004); *contra* Utility Br. 45. Pursuant to its longstanding practice, EPA considers several factors when assessing occurrence, including (1) comparing the available occurrence data to the health reference level; (2) the frequency with which the contaminant is found both alone

[8] Although EPA also fully supported its determination to individually regulate PFOA, PFOS, and PFHxS, no petitioner challenges these determinations. Accordingly, EPA does not discuss them here.

and co-occurring with other contaminants; (3) whether there is a "sustained upward trend" in occurrence; (4) "the geographic distribution (national, regional, or local occurrence)"; (5) the "impacted population, health effect(s), the potency of the contaminant, other possible sources of exposure, and potential impacts on sensitive populations or lifestages"; and (6) "production and use trends and environmental fate and transport parameters which may indicate that the contaminant would persist and/or would be mobile in water." JA-[RTC_3-29_to_3-30]; JA-[Reg_Det_Protocol_EPA-HQ-OW-2022-0114-3613_30-31]. EPA provided extensive analysis of these factors for the Index PFAS, both individually and collectively, to determine that the contaminants warrant regulation. JA-[Occurrence_Support_126-258, A-1_to_A-32].

Based solely on the Act's titling of drinking-water regulations as "national primary drinking water regulations," Petitioners attempt to rewrite the criteria of a "substantial likelihood that the contaminant will occur in public water systems with a frequency…of public health concern" to add a "national in scope" requirement. 42 U.S.C. § 300g-1(b)(1)(A)(ii); Utility Br. 44-45. Asserting that "considerable" is a synonym, for "substantial," Petitioners urge that "the likelihood of occurrence must be considerable in nature, and national in scope." Utility Br. 45. But this strained reading improperly both adds new terms and rearranges the statute's syntax to create an entirely *different* standard with a nonsensical requirement that

the "likelihood" have a "national scope." Utility Br. 44-45; *Abbott v. United States*, 562 U.S. 8, 25 (2010) (interpreting statutes to "make[] sense as a matter of syntax"). Because the statutory text imposes no geographic requirement for occurrence, the Court should not accept Petitioners' atextual interpretation. 42 U.S.C. § 300g-1(b)(1)(A)(ii); *Coal. for Renewable Nat. Gas*,108 F.4th at 852-53.

1. EPA Properly Considered State Monitoring Data.

When making its regulatory determinations, EPA reasonably relied on a "very large dataset consisting of tens of thousands of samples" from 32 state monitoring programs, "represent[ing] one of the most robust occurrence datasets ever used to inform the development of drinking water regulation of a previously unregulated contaminant." JA-[FR_32559]. Petitioners fail in their attempts to discount this data based on states' differing testing criteria and reporting levels and Petitioners' belief the data was not sufficiently "nationwide." Utility Br. 43-44; Industry Br. 50-51.

a. With respect to states' different testing methodologies, EPA carefully assessed the quality of the state data and fully explained the quality-control measures it undertook. JA-[RTC_6-10_to_6-19]; JA-[Occurrence_Support_23-29]. Specifically, EPA ensured that only finished drinking water (i.e., treated drinking water ready to be delivered to consumers) data was used and removed data not representing single types of PFAS. JA-[Occurrence_Support_23-29].

EPA then separated states' data into non-targeted statewide data and data collected from targeted areas where PFAS contamination was expected to have occurred and analyzed these datasets separately to ensure accurate characterization of the data. JA-[Occurrence_Support_23].

Petitioners argue that states' targeted data should be disregarded as "tainted," Industry Br. 45, 51, but there is nothing inappropriate about this data and ignoring it would arbitrarily exclude relevant information and known exposures to the contaminant. Although testing *only* where a state believes contamination exists may not reveal the full breadth of contamination within a state, it does provide critical information regarding the number of locations with known contamination, the number of people affected, whether the contamination is localized or geographically dispersed, and the levels of contamination in certain areas. This information is highly relevant, and EPA properly considered it.

Additionally, although different states reported occurrences at different thresholds, Utility Br. 43-44; Industry Br. 50, EPA accounted for the specific reporting thresholds of each state's data by analyzing both reported detections and detections above the health reference level. JA-[FR_32554-57]; JA-[Occurrence_Support_200]. While some states' higher reporting thresholds likely undercount the total number of detections in those states, this data still provides useful information on the scale and geographic dispersal of detections. Moreover,

by standardizing analysis through comparison to the health reference level, EPA further ensured that detections monitored at very low thresholds were not given undue weight.

Finally, Petitioners erroneously assert that, because some states reported HFPO-DA levels below the "practical quantitation level" set for this rule (*see* Pt.III.C), those states monitored at levels laboratories cannot accurately test. Utility Br. 44; Industry Br. 50. But the practical-quantitation level is not an assessment of a minimum accurate detection limit; it is a quantitation level that EPA believes can be achieved by "a broad spectrum of capable laboratories across the nation." JA-[Occurrence_Support_21]; *see also* JA-[RTC_6-13]. In fact, practical-quantitation levels are generally set "*above* the limit of detection," and for PFAS specifically, all the practical-quantitation levels were set "*well above their limits of detection*." JA-[FR_32574] (emphasis added). The fact that a state monitoring program used a lower reporting threshold than required in EPA's nationwide reporting thus does not call any reporting data into question. JA-[RTC_6-13].

b. Petitioners' concerns that the state data are not part of a nationwide monitoring program are similarly misplaced. Utility Br. 43. SDWA specifically contemplates EPA may consider data sources other than its own nationwide monitoring data. It requires only that EPA must consider "the best available public

health information, *including*"—but not limited to—"[EPA's nationwide] occurrence database established under 300j-4(g)" of the statute. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (emphasis added).

Here, the state data EPA considered was the "best available public health information" and fully demonstrated that HFPO-DA and PFNA individually and the Index PFAS collectively are present at levels of public health concern across disparate sections of the country. JA-[Occurrence_Support_126-251]; *contra* Utility Br. 43; Industry Br. 50. EPA considered data from 32 states, of which 30 states had data for PFNA and 25 states had data for HFPO-DA. JA-[FR_32554-55]; JA-[Occurrence_Support_23-29, 201-16]. This data came from geographically dispersed states and from both states with concentrated population centers and states that are predominantly rural. JA-[Occurrence_Support_23-29, 201-16]. Although it did not come from every single state, the data was sufficiently robust and representative to warrant EPA's consideration and reliance. *Id*.; JA-[FR_32553-32560, 32583, 32594-96]; JA-[RTC_6-10].

Additionally, although Petitioners assert that EPA previously declined to regulate a contaminant (acanthamoeba) as a drinking water contaminant based on the lack of nationwide data, Utility Br. 42, this is incorrect. EPA declined to regulate acanthamoeba through SDWA because the available public health data demonstrated that adverse health effects were not caused by contaminated drinking

water, but instead by "poor hygiene practices among contact lens wearers." 67 Fed. Reg. 38222, 38232 (June 3, 2002); JA-[RTC_3-38_to_3-39]. EPA's decision to issue a guidance document on acanthamoeba for contact lens wearers rather than issuing drinking water regulations, thus is entirely distinct from the circumstance presented here. 68 Fed. Reg. 42898, 42903 (July 18, 2003); https://www.epa.gov/sdwa/danger-using-tap-water-contact-lenses. Here, EPA reasonably relied on "one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant," JA-[FR_32559], to determine to regulate the Index PFAS.

2. EPA Reasonably Determined There Is a Substantial Likelihood HFPO-DA Will Occur at Frequencies and Levels of Public Health Concern.

EPA properly considered the "best available public health information, including [EPA's national] occurrence database" to find a substantial likelihood HFPO-DA will occur at frequencies and levels of public health concern. 42 U.S.C. § 300g-1(b)(1)(A)-(B). Additionally, when UCMR5 data became available after the preliminary regulatory determination and was raised in public comments, EPA properly considered the data and determined it confirmed EPA's prior analysis.

a. Substantial Evidence Supports EPA's HFPO-DA Occurrence Determination.

To determine that HFPO-DA occurs with a frequency and at levels of public health concern warranting regulation, EPA considered extensive data from 25 state

drinking water monitoring programs and data in its occurrence database from the Department of Defense and National Water Information System. JA-[Occurrence_Support_194-219, 252-58]. This data demonstrates that HFPO-DA currently occurs in concentrations above the health reference level in public water systems in at least five geographically diverse states and is currently detected in eight additional states. JA-[FR_32557]; JA-[Occurrence_Support_205-216]. Additionally, EPA found that, due to the environmental persistence of HFPO-DA, its "continued and increasing presence in consumer products and use," and the experience gleaned from the extraordinary persistence of other PFAS in the environment, "there is a substantial likelihood HFPO-DA will occur at a frequency and level of public health concern." JA-[FR_32557]. Despite this evidence, Petitioners incorrectly assert EPA had insufficient data to regulate HFPO-DA.

Industry Petitioners erroneously assert that, if the Court simply disregards the HFPO-DA contamination Petitioner Chemours caused in North Carolina, HFPO-DA rarely occurred elsewhere in the United States. Industry Br. 45, 50-51. Similarly, Utility Petitioners attempt to diminish the significance of HFPO-DA contamination in Kentucky by noting that that contamination *also* may have been caused by Petitioner Chemours's Washington Works HFPO-DA plant across the state border in West Virginia. Utility Br. 47-48; Industry Br. Add. B14. But neither set of petitioners explains why either EPA or this Court should disregard

significant occurrences of drinking water contamination at levels of public health concern in these states simply because Petitioner Chemours—which still manufactures HFPO-DA at both plants, Industry Br. Add. B14—may have caused the contamination.

Moreover, North Carolina and Kentucky were not the only states with drinking water contaminated by HFPO-DA. JA-[Occurrence_Support_206-213]. Michigan, Ohio, and Virginia also reported public water systems with HFPO-DA contamination above the health reference level; and public water systems in eight additional states, including Vermont, Alabama, and Colorado, detected HFPO-DA at lower levels. JA-[Occurrence_Support_211-213].

Not only do these disparate locations demonstrate HFPO-DA contamination is not limited to a single locality or region, *contra* Utility Br. 48, but Petitioner Chemours does not appear to have facilities in many of these states. *See* https://www.chemours.com/en/about-chemours/global-reach. This suggests that contamination comes from more than just Petitioner Chemours's HFPO-DA production facilities, and potentially comes from consumer products containing HFPO-DA. JA-[Occurrence_Support_194]. EPA rested its regulatory determination not only on data demonstrating HFPO-DA's current occurrence, but also on the "substantial likelihood" that the contaminant "*will* occur in public water systems with a frequency and at levels of public health concern" in the future. 42

U.S.C. § 300g-1(b)(1)(A)(ii) (emphasis added). EPA explained that, because HFPO-DA continues to be produced domestically and has a "continued and possibly increasing presence in consumer products and use," and because it is "very stable chemically" and resistant to degradation, it will continue be present in the environment in increasing amounts. JA-[FR_32557]; JA-[Occurrence_Support_198].

Notably, neither set of Petitioners disputes HFPO-DA's persistence and accumulation in the environment, or that HFPO-DA continues to enter the environment through both production of the chemical and consumer products containing the chemical. Because the current data demonstrates occurrence at a frequency and level of public health concern, and because the current data represents the nadir of HFPO-DA occurrence, EPA reasonably determined there is a "substantial likelihood [HFPO-DA] *will* occur…at a frequency and at levels of public health concern" in the future. 42 U.S.C. § 300g-1(b)(1)(A)(ii) (emphasis added); JA-[FR_32557].

b. EPA Properly Limited Its Consideration of the Partial UCMR5 Data.

Petitioners incorrectly assert EPA was required to rely on UCMR5 data in making its regulatory determination for HFPO-DA. Industry Br. 44-50. But SDWA requires only that EPA consider the "best available public health information, including the occurrence database established under section 300j-

4(g)...." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). Because the UCMR5 data was not "available" data, much less the "best available" data, the Act did not mandate reliance on it. *Id*.

i. At the outset, Petitioners erroneously equate EPA's "occurrence database" referenced in SDWA with UCMR data. *Compare* Industry Br. 45; Utility Br. 41 *with* 42 U.S.C. § 300j-4(g)(1). The occurrence database is broader than UCMR data; it also includes, for example, Department of Defense and National Water Information System data that EPA explicitly analyzed as part of this rulemaking. *Compare* https://www.epa.gov/sdwa/national-contaminant-occurrence-database-ncod; *with* JA-[Occurrence_Support_217-19].

Moreover, at the time of EPA's preliminary regulatory determination, no UCMR5 data existed, and thus *no* data was "available." JA-[NPRM_18638]; JA-[Occurrence_Support_252]. Petitioners argue that an entirely different provision of the statute requiring occurrence-database information be made "available to the public in readily accessible form," 42 U.S.C. § 300j-4(g)(5), transforms the Act's requirement that EPA use the "best available" data into a requirement to *wait* specifically for UCMR data. Industry Br. 48. But this is inconsistent with the plain text of the statute.

Nothing in the statute requires EPA to include a contaminant in UCMR monitoring prior to regulation, or to await nationally representative UCMR results

for a contaminant before beginning the regulatory process. JA-[RTC_6-68]; 42 U.S.C. § 300g-1. The Act simply states that EPA must consider "the best *available* public health information, *including* the occurrence database...." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II) (emphases added). Industry Petitioner's attempt to rewrite the statute to require that EPA consider "the best available...information, including [*UCMR data for the specific contaminant, which must exist in*] the occurrence database" strains the text too far. That no UCMR data for HFPO-DA was present in the database at the time of the proposed regulatory determination does not preclude EPA from evaluating other occurrence information to assess the "substantial likelihood" that a contaminant "will occur…with a frequency and at levels of public health concern." *Id*. § 300g-1(b)(1)(A).

Consistent with its statutory obligation, EPA considered "the best available public health information, including"—but not limited to—"the occurrence database." 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II). EPA thus properly considered HFPO-DA data available in the occurrence database—Department of Defense data and National Water Information System data—as well as data from 25 state monitoring programs. JA-[Occurrence_Support_199-219].

ii. Petitioners incorrectly assert EPA should have relied exclusively on the partial UCMR5 data showing very little detection of HFPO-DA in the small number of samples EPA had received by the date of the rulemaking, *instead of* the

substantially more robust state monitoring data that demonstrated HFPO-DA contamination above the health reference level in five states ranging from Michigan to Virginia, and detections as far west as Colorado. Industry Br. 50; JA-[Occurrence_Support_206-210]. Petitioners argue the state monitoring data should be ignored in favor of the partial UCMR5 data because they erroneously claim the state data had fewer samples from fewer public water systems. Industry Br. 50. But the state monitoring data produced over twice as many samples as the partial UCMR5 data had reported—over 35,000 state samples, compared to 16,777 UCMR5 samples available at the time of the final regulatory determination. JA-[Occurrence_Support_205-07, 211-13, 252]. Moreover, the state data monitored nearly three times as many water systems as had been reported in the partial UCMR5 data—over 10,000 water systems in the state monitoring compared to 3,722 reported in the partial UCMR5 data. JA-[Occurrence_Support_205-07, 211-13, 252]. The state data thus was the "best available" data. 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).

iii. Although Petitioners argue that HFPO-DA should not be regulated because it is largely not present in most of the limited set of UCMR5 samples available, Industry Br. 46, this partial data provides no conclusion regarding the potential occurrence or lack thereof of HFPO-DA nationwide. The partial UCMR5 data is not reflective of all systems for populations over 3,300 or a "representative

sampling" of nationwide systems serving 3,300 or fewer people, as required by the statute. 42 U.S.C. § 300j-4(g)(7)(A)-(B) *as amended by* Pub. L. 115-270, § 2021 (2018), 132 Stat. 3765, 3861. As of the time of the rulemaking, only approximately *one-third* of systems had reported collection of even *one* sample. JA-[FR_32601].

This partial UCMR5 data cannot support a determination that HFPO-DA does *not* occur frequently, particularly in light of the state data. As EPA explained, "[i]t is difficult to determine that a contaminant is *not* occurring or *not* likely to occur based on non-national data because the data are limited in scope and the contaminant could be occurring in other parts of the country that have not been monitored." JA-[Reg_Det_Protocol_21] (emphasis added). In contrast, "a compilation of non-national data sources *can* support a determination that there *is* a substantial likelihood that the contaminant will occur in [public water systems] with a frequency and at levels of public health concern." JA-[Reg_Det_Protocol_21] (emphasis added; quotations omitted); *see NRDC v. EPA*, 529 F.3d 1077, 1086 (D.C. Cir. 2008) (affording EPA "wide latitude in determining the extent of data-gathering necessary to solve a problem" and "defer[ring] to an agency's decision to proceed on the basis of imperfect scientific information" (internal quotations omitted)).

The partial UCMR5 data demonstrates neither the existence nor absence of occurrence of HFPO-DA at frequencies and levels of public health concern because there simply is not a representative enough sample to draw conclusions. In contrast, the state data definitively demonstrates that HFPO-DA is currently present in at least 13 states and is currently present at levels of public health concern in at least 5 states. JA-[Occurrence_Support_205-216]. EPA cannot reasonably ignore valid and complete data demonstrating that HFPO-DA *does* occur in five geographically dispersed states at levels of public health concern.

iv. Similarly, Petitioners incorrectly assert that the Department of Defense and National Drinking Water Information System data in the occurrence database "confirm the UCMR5 data that HFPO-DA does not occur frequently in public water systems." Industry Br. 49. But this non-state data simply shows that HFPO-DA did not occur at those particular test sites. JA-[Occurrence_Support_216-19]. This data does not negate state data demonstrating other sites where contamination is known to occur.

v. Finally, contrary to Petitioners' assertion, EPA did not "refus[e] to consider" the UCMR5 data. Industry Br. 47. Although not required to do so, EPA fully considered the available data as well as its limitations. JA-[FR_32557, 32559, 32601-05]; JA-[Occurrence_Support_252-58]; JA-[RTC_6-68_to_6-101]. EPA explained that, although the UCMR5 data was "not available for this rule's

proposal, [was] not complete, and [was] not a basis for informing the agency's decisions for the final rule," the data "generally confirm[ed] the extensive occurrence analyses the agency has conducted: namely, that all six regulated PFAS occur in finished drinking water and that the six regulated PFAS co-occur with one another." JA-[FR_32601]. For HFPO-DA specifically, although less than one-quarter of UCMR5 data was available, the data showed 17 water systems reporting HFPO-DA detections, with one water system exceeding the level of public health concern, thus confirming its occurrence. JA-[Occurrence_Support_252-53]; JA-[RTC_6-69]. Because this data was insufficiently comprehensive to demonstrate the presence or absence of occurrence *anywhere* in the country and does not represent the "best available public health information," and because extensive state data demonstrates HFPO-DA occurrence in geographically dispersed areas of the country, EPA reasonably determined there is a substantial likelihood HFPO-DA will occur at frequencies and levels of public health concern.

3. EPA Reasonably Determined There Is a Substantial Likelihood PFNA Will Occur at Frequencies and Levels of Public Health Concern.

EPA considered the "best available" data from UCMR3, state monitoring, Department of Defense monitoring, and National Water Information System data when determining to regulate PFNA.

a. Petitioners argue EPA erred in relying on UCMR3 data because that data was reported at minimum levels *higher* than the health reference levels at issue in this rulemaking. Utility Br. 42-43. But this simply means that the UCMR3 likely *underreported* the frequency of occurrence of the Index PFAS, and PFNA specifically. Public water systems in seven states reported detections of PFNA over 20 ng/L—twice the 10 ng/L health reference level in EPA's regulatory determination. JA-[FR_32556]. Thus, based solely on the UCMR3 data, PFNA occurs in public drinking water at a minimum of *double* the concentration EPA deems the "level of public health concern" at systems in at least those seven states. JA-[FR_32556].

b. Extensive state monitoring data at reporting thresholds lower than the UCMR3 further demonstrates that PFNA occurs at a frequency and levels of public health concern well beyond a single region of the country; it has been detected in 19 states and detected at levels above the health reference level in 12 states. JA-[Occurrence_Support_174-87]; *contra* Utility Br. 49-50. The 12 states with concentrations above the health reference level are geographically diverse, ranging from Maine to Alabama. JA-[Occurrence_Support_174-187]. Similarly, Department of Defense data identified eleven military bases in which PFNA was detected in water samples, two of which—in South Dakota and in Texas—had detections above the health reference level. JA-[Occurrence_Support_189-90]. In

short, ample evidence demonstrates PFNA currently occurs, and there is a substantial likelihood it will occur, at a frequency and level of public health concern throughout the United States.

c. Finally, although eight PFNA manufacturers committed to cease PFNA production in the United States by 2015, legacy stock may still be used domestically, products manufactured prior to 2015 may still contain PFNA, and products made with PFNA may be manufactured abroad and imported into the United States. JA-[FR_32556]; JA-[Occurrence_Support_160]. Additionally, other chemicals break down into PFNA. JA-[FR_32536]. And PFNA is "very stable chemically" with a "resistance to essentially all forms of degradation other than atmospheric processes." JA-[Occurrence_Support_162-63]. PFNA thus is very persistent in the environment. Accordingly, "there is a substantial likelihood that environmental contamination of sources of drinking water [with PFNA] will continue." JA-[FR_32556]. Given these factors, EPA reasonably found there is a substantial likelihood that PFNA will occur at a frequency and levels of public health concern. JA-[FR_32556-57].

4. EPA Reasonably Determined There Is a Substantial Likelihood Mixtures of the Index PFAS Will Occur at Frequencies and Levels of Public Health Concern.

EPA analyzed state monitoring data and determined there is a substantial likelihood that mixtures of the Index PFAS will co-occur at frequencies and levels

of public health concern. JA-[Occurrence_Support_220-46]; JA-[FR_32590-600]. EPA considered the frequency with which two or more PFAS are detected together and detected together above the health reference level in reported data. JA-[Occurrence_Support_220-35]. EPA then also conducted a statistical analysis of the data that further demonstrates the odds of finding one Index PFAS increase substantially when a second Index PFAS is present. JA-[Occurrence_Support_238-46].

a. EPA Properly Considered Reported Co-Occurrences of Index PFAS.

Twenty-one of 27 states reported combinations of two or more Index PFAS occurring above the health reference level. JA-[Occurrence_Support_220-35]; *contra* Utility Br. 51-52 (asserting EPA only considered "mere detections…irrespective of their concentrations"). Petitioners incorrectly argue that co-occurrence should only matter if the individual contaminants co-occur at levels at which *each* contaminant exceeds its individual health reference level. Utility Br. 51-53. But this misunderstands the purpose of regulation of the chemicals as a hazard index as opposed to individually. As explained in Pt.II.B, *infra*, because these chemicals all elicit the same or similar health effects, combinations of even very low doses of these chemicals can result in more harmful effects than if the chemicals occurred alone. JA-[RTC_4-368_to_4-371, 4-418_to_4-419]. Regulation via a hazard index is thus necessary to protect against

the health effects of exposure to combinations of the Index PFAS. JA-[RTC_4-424_to_4-425].

b. EPA Reasonably Statistically Analyzed Index PFAS Co-Occurrence.

EPA conducted extensive statistical analysis of the occurrence of the Index PFAS and found the Index PFAS are likely to co-occur. EPA calculated the odds ratio[9] for every pair of Index PFAS using the non-targeted state data, which demonstrates the Index PFAS are between 5.2 and 66.0 times more likely to occur in mixtures of two or more Index PFAS than they are to occur alone. JA-[Occurrence_Support_243-44].

Petitioners ignore the entirety of EPA's statistical analysis of state monitoring data and focus exclusively on perceived lack of occurrences in EPA's purely illustrative analysis of the partial UCMR5 data. Industry Br. 40. At the

[9] Odds ratios "represent the change in the odds of observing a first chemical given that a second chemical is known to be present relative to the odds of observing the first chemical given that the second chemical is not present." JA-[Occurrence_Support_242]. This is different than calculating the probability of occurrence (or "odds"). *Contra* Industry Br. 40. Odds ratios greater than 1 indicate increasingly higher likelihoods of finding the first chemical if the second chemical is present than if it were not present. An odds ratio of 1 indicates that there is the exact same likelihood of finding the first chemical if the second chemical is present as if it were not present (i.e., there is no relationship between the odds of finding the two chemicals). Odds ratios between 0 and 1 indicate a greater likelihood of *not* finding the first chemical if the second chemical is present. And an odds ratio of 0 indicates missing data in the formula such that there is a null set. JA-[Occurrence_Support_242].

outset, EPA's regulatory determination is based on its analysis of state data, not UCMR5 data, for the reasons outlined in Pt.II.A.2.b *supra*. JA-[Occurrence_Support_252] ("Since the UCMR5 dataset is currently incomplete, it does not serve as the basis for informing the agency's decisions for the regulatory determinations and [regulations]."). Nevertheless, because EPA received comments on the preliminary UCMR5 data that had begun to be reported between the preliminary and final regulatory determinations, EPA conducted a purely illustrative analysis of the UCMR5 data. JA-[Occurrence_Support_252-58]. Because this data did not form the basis of EPA's determination, Petitioners' arguments are irrelevant. Moreover, Petitioners misstate the data in a number of respects.

First, by focusing on instances where all Index PFAS are present, Petitioners misunderstand the hazard index. Industry Br. 40. As EPA explained, the hazard-index approach addresses the fact that "where drinking water contains any combination of *two or more* of the four PFAS that are the subject of this action—PFHxS, PFNA, HFPO-DA, and PFBS—the hazard associated with each PFAS in the mixture must be added together to determine whether the mixture exceeds a level of public health concern." JA-[RTC_4-418] (emphasis added).

Second, Petitioners are wrong that "[c]o-occurrence of even three of the Index [PFAS] is extremely rare" and "EPA has not identified a single sample

containing detectable levels of all four Index Substances occurring together." Industry Br. 40. The state data identifies 31 samples across 20 systems (1% of systems) in which all four Index PFAS were present, and an additional 1,919 samples across 362 systems (25.9% of systems) in which three Index PFAS were present. JA-[Occurrence_Support_240]. Moreover, given that only approximately one-third of systems had reported *any* UCMR5 data, it is not surprising or relevant that the mere 24 samples containing HFPO-DA in that data did not happen to contain *all* other Index PFAS. JA-[Occurrence_Support_252]; JA-[FR_32601].

Third, Petitioners' assertion that "EPA admits that odds of co-occurrence of [HFPO-DA and PFNA] are 0.0%," with a citation to odds *ratios* at JA-[Occurrence_Support_256] both misstates the data and fundamentally misunderstands the difference between "odds" and an "odds ratio." Industry Br. 40. As explained in n.9 *supra*, these are different concepts, and the odds ratio cannot be expressed as a percentage. An odds ratio of 0 demonstrates a null dataset, not a lack of probability of co-occurrence. *See* n.9. Moreover, EPA's analysis of the state data demonstrates an odds ratio of 15.9 for these two chemicals, meaning that it is 15.9 times more likely that PFNA will be present if HFPO-DA is present. JA-[Occurrence_Support_243].

Finally, EPA did not dilute the "substantial likelihood" standard by adding in "enough compounds to the hazard index" to "always claim the occurrence

criterion is met." *Id*. As fully explained in Pt.II.B, *infra*, EPA carefully considered inclusion of these specific Index PFAS to ensure sufficient similarity in the systems and tissues affected by the chemicals, and EPA's extensive co-occurrence analyses here demonstrate the high likelihood that at least two of these chemicals will co-occur at frequencies and levels of public health concern. EPA thus fully supported its determination to regulate the Index PFAS as mixtures.

B. The Record Supports EPA's Determination that the Index PFAS May Have an Adverse Effect on the Health of Persons.

The record fully supports EPA's determination that combinations of two or more Index PFAS "*may* have an adverse effect on the health of persons." 42 U.S.C. § 300g-1(b)(1)(A)(i) (emphasis added). In keeping with SDWA's health-protective focus, this threshold is not onerous; it does not require definitive proof, but rather a reasonable *possibility* of adverse health effects. *Fed. Trade Comm'n v. Morton Salt Co.*, 334 U.S. 37, 46 (1948) (interpreting statute's use of "may" to require "only that there is a reasonable possibility that they 'may' have had such an effect"). The record evidence here easily meets this standard by demonstrating that the four Index PFAS have the same or similar health effects.

EPA explained that each of the four Index PFAS "can disrupt signaling of multiple biological pathways, resulting in a shared set of adverse effects...." JA-[FR_34545]. Exposure to each of these chemicals elicit many adverse health effects, including effects on development, the liver and kidney, and endocrine,

respiratory, and reproductive systems. JA-[MCLG_1-8]; JA-[FR_32552]; JA-[RTC_4-373_to_4-375, 4-428]. Although each chemical's individual health reference level is set based on its most sensitive health effect (its "critical effect"), exposure to each of these chemicals causes many of the same adverse health outcomes. JA-[MCLG_1-8_to_1-10, 2-1_to_2-5, 2-8, 2-11]. For example, exposure to each of the four PFAS leads to endocrine, liver, and kidney toxicity. JA-[MCLG_1-8_to_1-10]. EPA thus reasonably determined that these chemicals are dose-additive. JA-[Framework_33-34] ("[I]t is considered a health-protective conclusion that PFAS that can be demonstrated to share one or more...adverse health outcomes will produce dose-additive effects from co-exposure."). Petitioners assert three challenges to this framework, none of which is availing.

1. Petitioners misstate both the Science Advisory Board's recommendations and the science underlying EPA's dose-additivity analysis. Petitioners incorrectly assert that the Board advised that EPA's "dose[-]additivity assumptions...cannot sanction regulation." Industry Br. 41. In fact, the Board explicitly supported consideration of PFAS dose-additivity. JA-[SAB-Report_90] (The Board PFAS Review Panel "supports dose[-]additivity based on a common outcome, instead of a common mode of action as a health protective default assumption and does not propose another default approach."). The Board *never*

suggested that the Index PFAS dose-additivity "cannot sanction regulation." *Id*; *contra* Industry Br. 41.

Petitioners further misstate the science supporting EPA's dose-additivity analysis by asserting that EPA relied exclusively on studies of PFAS that did not include the Index PFAS and that "none of the relied-upon studies evaluates the specific mixtures regulated by EPA's hazard index here." Industry Br. 41. At the outset, the hazard-index approach does not regulate only when all four Index PFAS are present; it regulates mixtures of two or more Index PFAS. JA-[RTC_4-418]. And EPA detailed numerous studies of various mixtures of the Index PFAS. JA-[Framework_33-37]; JA-[RTC_4-368_to_4-371]. Based on both studies of the individual Index PFAS and their various mixtures, EPA determined the Index PFAS likely are dose-additive. JA-[Framework_38] ("PFAS data reported in the literature support an assumption of similarity in toxicity profiles for several health effect domains.").

2. Petitioners next erroneously assert that dose-additivity pertain *only* when there is "an overlap of critical effects." Industry Br. 41-42. But the sole document Petitioners cite for this position explicitly endorses use of the hazard index with substances with *different* critical effects, explaining an index in these circumstances is "health-protective" because it "increases the confidence of a minimal hazard...." JA-[Adv_Dose_Add_EPA-HQ-OW-2022-0114-3122_2-26].

Importantly, EPA need only establish the contaminant "*may* have an adverse effect on the health of persons." 42 U.S.C. § 300g-1(b)(1)(A)(i) (emphasis added).

A "critical effect" in the context of developing a reference dose is the effect "typically observed at the lowest tested dose among the available data." JA-[FR_32547]; *contra* Industry Br. The critical effect is not the *only* effect of the chemical, or even the only effect at low levels. For example, EPA selected liver effects as the critical effect for HFPO-DA, but exposure to HFPO-DA also elicits many additional adverse health effects, including increased kidney weight. JA-[MCLG_1-8_to_1-10, 2-1_to_2-2]; *see also* Pt.III.E, *infra*. Similarly, EPA selected the thyroid as the most critical effect for PFBS, but PFBS exposure also elicits many other adverse effects, including increased kidney weight. JA-[MCLG_1-8_to_1-10, 2-4_to_2-5]. Because *both* these chemicals affect the kidney, exposure even at levels that individually would not likely result in adverse effects, may result in adverse kidney effects when exposure to both chemicals occurs simultaneously. JA-[RTC_4-368_to_4-378, 4-497_to_4-498]. EPA cites a multitude of studies demonstrating this. JA-[RTC_4-368_to_4-378]; JA-[Framework_33-37]. Notably, Petitioners cite no scientific evidence disproving the dose-additivity of these chemicals.

3. Finally, Petitioners assert that the Index approach is "novel" and overly broad. Industry Br. 43-44. To the extent Petitioners intend these vague

criticisms, combined with a single case citation, to invoke the major questions doctrine, Petitioners have failed to preserve this argument. Industry Br. 44 (citing *UARG v. EPA*, 573 U.S. 302, 324 (2014)); *Consol. Edison Co. of New York, Inc. v. FERC*, 347 F.3d 964, 970 (D.C. Cir. 2003) (argument only "hint[ed] at" in the opening brief deemed waived). Moreover, as fully explained in Pt.I.A, *supra*, far from an "extraordinary case" departing from longstanding practice, EPA's use of the hazard index here is in line with its longstanding "history" of regulating contaminants in groups and is not a new grant of authority of "economic and political significance." *West Virginia v. EPA*, 597 U.S. 697, 721 (2022). Moreover, the PFAS combined here are not an "overly broad" assertion of authority. The Index PFAS are chemically and structurally similar compounds that affect the same health endpoints and have been shown to co-occur in drinking water with considerable frequency. JA-[FR_32552, 32592-93]; JA-[NPRM_18642-43]. They thus are amenable to regulation via a hazard index, and their regulation falls within the heartland of EPA's regulatory authority.

III. The Rule's Standards Are Lawful, Reasonable, and Supported by the Record.

Each of Petitioners' myriad challenges to the Rule's Standards fail. As to PFOS and PFOA, the record demonstrates that these Standards meet the Act's requirement to be as close to the Goals as "feasible," and that EPA addressed Petitioners' comments regarding regulatory alternatives. As to Index PFAS

mixtures, the Act authorizes EPA to promulgate Standards in the form of a hazard index, and EPA supported its selection of this Standard as an appropriate tool to address the dose-additive effects of these four PFAS. As to HFPO-DA, EPA considered and reasonably rejected each of Petitioners' objections, and EPA's conclusions on these scientific issues merit deference. Finally, EPA adequately consulted its Science Advisory Board before proposing the Standards.

A. EPA Set the Standards for PFOS and PFOA at the Level That Is as Close to the Goals as Feasible.

While no Petitioner challenges the Goals EPA set for PFOS and PFOA, Industry Petitioners dispute whether EPA set the final Standards closer to those Goals than "feasible."[10] Industry Br. 23-27. EPA's feasibility determination for the final Standards of 4.0 ng/L was reasonable, and the record demonstrates that EPA considered and addressed the very concerns Industry Petitioners raise here.

EPA must set the Standard for a contaminant "as close to the [Goal] as is feasible." 42 U.S.C. § 300g-1(b)(4)(B). For purposes of this analysis, "feasible" means:

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[10] Notably, Utility Petitioners—whose members include the public water systems that actually have to implement the Rule—do not challenge whether the PFOS and PFOA Standards are feasible within the meaning of SDWA. While their brief includes a throwaway reference to feasibility, Utility Br. 53-54, their arguments only concern EPA's finding that the Rule's benefits justify its costs, which is distinct from the feasibility determination under 42 U.S.C. § 300g-1(b)(4)(B). *See infra* Pt.IV.A; *City of Portland v. EPA*, 507 F.3d 706, 712 (D.C. Cir. 2007).

> feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration).

Id. § 300g-1(b)(4)(D). In other words, "feasible" means "technically possible and affordable." *City of Portland*, 507 F.3d at 712 (citing *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 509-512 (1981)). While this analysis does not entail balancing costs against benefits, pursuant to Congress's express guidance, EPA considers cost in this analysis by considering whether the costs of compliance are affordable for large public water systems. *Id.*; *see also* H.R. Rep. No. 93-1185, at 18, 1974 U.S.C.C.A.N. 6454, 6470-71 (stating Committee's intent that feasibility determinations are "to be based on what may reasonably be afforded by large metropolitan or regional public water systems").

In addition to evaluating the feasibility of *treatment* to the level of the Standard, EPA also considers "the *analytical limits* of [the] best available treatment and testing technology." JA-[FR_32573] (emphasis added) (quoting S. Rep. No. 104-169, at 3 (1995)); *see Int'l Fabricare*, 972 F.2d at 399 ("Before the EPA can set the enforceable limit…it first must ascertain how low a concentration of that chemical reliably can be measured[.]"). By considering these analytical limitations, EPA "ensure[s] that any public water system nationwide can monitor, determine compliance, and deliver water that does not exceed" the Standard. JA-[FR_32573].

EPA supported its Standards for PFOS and PFOA through a robust feasibility analysis. *See generally* JA-[FR_32573-78]; JA-[RTC_5-44_to_5-50, 5-164_to_5-165, 5-316_to_5-317]. Far from limiting its analysis to the "two sub-issues" Petitioners identify, Industry Br. 24, EPA considered all aspects relevant to determining what level is as close as feasible to each contaminant's Goal. First, EPA identified the lowest levels at which PFOA and PFOS can be "reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions" using EPA-approved methods, known as the practical-quantitation level. JA-[FR_32573]. For contaminants with a Goal of zero (like PFOS and PFOA), EPA commonly sets the Standard at the contaminant's practical-quantitation level so long as treatment to that level is otherwise feasible. *Id.*; *see Int'l Fabricare*, 972 F.2d at 398-400 (upholding Standard based on this methodology). Here, EPA considered laboratories' current technical capabilities and found that they can reliably detect and quantify PFOS and PFOA at a level of 4.0 parts per trillion. JA-[FR_32574-76]; JA-[RTC_5-44_to_5-46]. Petitioners do not challenge EPA's identification of the practical-quantitation level.

Second, EPA evaluated the best available technologies for removing PFOS and PFOA from drinking water and concluded that several technologies, including granular activated carbon, are available and effective under field conditions for

treating these contaminants to levels below the Standards. JA-[FR_32577, 32622-24]; JA-[RTC_5-316_to_5-317]; JA-[Best_Available_Tech_EPA-HQ-OW-2022-0114-3087]. EPA concluded that the costs of these technologies are reasonable at a system and national level. JA-[FR_32575]; JA-[RTC_5-164_to_5-165]. And in any event, the Act provides that use of granular activated carbon is *per se* "feasible" for the control of synthetic organic chemicals, which include PFAS. 42 U.S.C. § 300g-1(b)(4)(D); JA-[FR_32575]. Petitioners do not challenge EPA's identification of the best available technologies or its conclusion that these technologies are affordable for public water systems.

Third, EPA evaluated numerous other practical concerns regarding the Standards' implementation, including available laboratory capacity for sample analysis and disposal costs associated with treatment technologies. *See* JA-[FR_32575-77]. EPA considered each of these issues and explained why they did not alter its conclusion that the Standards are feasible.

Industry Petitioners claim that EPA failed to adequately respond to two of these practical concerns: the supply of materials and personnel to build and operate treatment technologies, and the sufficiency of laboratory capacity to analyze systems' compliance with the Standards. Industry Br. 25-27. EPA considered and responded to both these concerns. Regarding the supply of treatment materials and personnel, EPA acknowledged the possibility of short-term issues but did not

merely "assume[] without explanation that these problems would simply resolve themselves."[11] Industry Br. 26. Instead, EPA relied on record evidence—including comments from treatment-system suppliers—showing excess capacity and investment in expanded production. JA-[FR_32623]; JA-[RTC_10-201_to_10-202, 10-209]. EPA also noted the availability of federal funding to support operator training and certification programs. JA-[RTC_12-15].

While EPA *also* projected that increased demand for treatment will lead to supply increases and innovation, that was not the only factor supporting its decision, and it was based on EPA's experience with multiple rulemakings rather than mere speculation. JA-[RTC_10-202]. And in any event, the Act does not preclude EPA from relying on reasonable projections of technology availability. Indeed, Congress in 1986 removed the Act's previous requirement that Standards reflect "generally available" technology, indicating that EPA may base Standards on technology that is not currently in widespread use. *Id.*

Regarding available lab capacity, EPA reasonably explained its conclusion that adequate capacity exists to support implementation of the Standards. First, EPA noted that 53 labs spread throughout the country are already accredited for use of EPA's PFAS testing methods as part of the UCMR5 sampling program. JA-

[11] EPA extended the Standards' compliance deadline by two years to mitigate any potential supply chain issues and spread out peak demand for capital improvements. *See* JA-[FR_32632-33].

[RTC_5-47]. Those 53 labs have sufficiently accommodated the testing needs of UCMR5, which requires quarterly or semi-annual sampling by *every* medium and large system in the United States and by 800 smaller systems. *Id.* Second, apart from the labs approved to participate in UCMR5, EPA identified an additional 25 labs accredited for use of the relevant test methods. JA-[RTC_5-48]. Third, EPA noted that unlike the more frequent sampling required in UCMR5, many systems will qualify for reduced monitoring under this Rule and will only need to submit samples for analysis annually or triennially, easing the burden on laboratory capacity. *Id.* Fourth, EPA projected that laboratory capacity will grow in response to the Rule and state monitoring efforts. *Id.* And fifth, the final Rule allows systems to submit previously collected data to meet their initial monitoring requirements, potentially easing the Rule's testing burden by tens of thousands of samples. *See* JA-[FR_32616]. EPA's conclusions were corroborated by the commercial environmental testing community, which represented that laboratory capacity is not expected to be an "ongoing concern." *Id.*

Finally, EPA responded to commenters claiming it had overestimated the number of commercial labs accepting samples for analysis. Industry Br. 26-27. In particular, EPA noted that the database on which commenters relied excludes laboratories in some states and likely underestimates the actual number of accredited or certified commercial labs. JA-[RTC_5-47].

Accordingly, EPA addressed all of Industry Petitioners' concerns and reasonably concluded that the Standards for PFOS and PFOA are feasible.

B. EPA Adequately Considered Alternative Standards.

EPA also addressed Industry Petitioners' comments suggesting that EPA consider specific alternative Standards for PFOS and PFOA. Industry Br. 27-30. At the outset, the Act does not require EPA to consider any particular number or range of alternatives to the Standards it proposes. It simply provides that *if* EPA elects to consider alternatives as part of its rulemaking, it must analyze the incremental costs and benefits of those alternatives in the Economic Analysis required under Section 300g-1(b)(3)(C). 42 U.S.C. § 300g-1(b)(3)(C)(i)(III). Petitioners do not dispute that EPA satisfied that requirement for the alternatives it considered of 5.0 and 10.0 parts per trillion, *see* JA-[FR_32634], and their objections to how EPA selected those alternatives over other potential alternatives are legally irrelevant. *See* Industry Br. 29-30.

At bottom, Industry Petitioners simply complain that EPA did not sufficiently consider their preferred regulatory alternatives of 20 and 40 ng/L for PFOA and PFOS, respectively. Industry Br. 28. But EPA met its burden to respond to these public comments and provided a reasoned explanation for rejecting these alternative Standards. Industry Petitioners suggested these levels because they reflected the minimum reporting levels for PFOS and PFOA adopted

in 2012 for the UCMR3 sampling program.[12] *See* JA-[ACC_Comments_EPA-HQ-OW-2022-0114-1841_at_53]; 77 Fed. Reg. 26072 (May 2, 2012). EPA explained that in the 12 years that had elapsed since 2012, analytical accuracy and precision had improved such that 20 and 40 ng/L no longer represented the analytical limits of the best available technology. JA-[RTC_5-198]; *see also* JA-[RTC_13-524]; JA-[FR_32574] (noting use of 4.0 ng/L as minimum reporting levels for more recent UCMR5). Given the Act's command to set the Standards "as close to the [Goals] as is feasible," EPA reasonably decided not to consider alternative Standards based on outdated analytical limits. 42 U.S.C. § 300g-1(b)(3)(A), (b)(4)(B).

Industry Petitioners suggest that EPA nonetheless should have considered their preferred alternatives because EPA could have selected them as the closest "feasible" levels to the Goals based on their "incremental costs" compared to the final Rule's Standards. Industry Br. 28-29. But Petitioners appear to be conflating the "feasibility" analysis required by Section 300g-1(b)(4)(B) with EPA's separate requirement to conduct an Economic Analysis and determine whether a Standard's benefits justify its costs under Section 300g-1(b)(3)(C) and (b)(4)(C). As

[12] In their brief, Industry Petitioners also argue (apparently for the first time) that an EPA guidance document supports their preferred alternative Standards. Industry Br. 28. Petitioners do not explain how their cited guidance—which addresses how to conduct animal toxicity studies for purposes of a different statute—is relevant to setting Standards under the Act.

discussed in Pt.IV.A, *infra*, these are two distinct requirements, and feasibility under the Act does not depend on the incremental costs or benefits of one alternative Standard compared to another. As this Court recognized in *City of Portland*, "[n]othing in Section 300g-1(b)(4)…allows EPA to choose a [Standard] other than the most stringent feasible." 507 F.3d at 712 (holding "feasible" simply means "technically possible and affordable"). Accordingly, there is no conflict between EPA's decision not to consider these alternatives and its obligation to determine what Standard is feasible.

C. EPA Has Authority to Promulgate Standards in the Form of a Hazard Index.

For mixtures containing two or more of the Index PFAS, EPA promulgated a Goal and Standard in the form of a hazard index. JA-[FR_32571, 32580]. No Petitioner challenges whether the Standard selected is "as close to the [Goal] as feasible." 42 U.S.C. § 300g-1(4)(A), (B). Instead, they simply challenge the *form* of the Standard. Utility Br. 34-36. Contrary to their arguments, the best reading of the statutory term "maximum contaminant level" clearly authorizes EPA's selection of a hazard index as the Standard, and the hazard index approach is consistent with Standards EPA has promulgated for other contaminants. *Loper*, 144 S. Ct. at 2266.

Nothing in the Act requires a Standard to take any particular form. JA-[RTC_5-386]. Instead, a Standard that sets a "maximum contaminant level"

simply must state "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." 42 U.S.C. § 300f(3). To meet this definition, a Standard must specify a "level" for the relevant contaminant. JA-[RTC_5-386]. And for practical purposes, it must be capable of being validated to assess a system's compliance. *Id.* The hazard index in the final Rule satisfies these requirements. It establishes the level that the relevant contaminant—here, any mixture of two or more Index PFAS—may not exceed in drinking water. And it can be validated because regulated systems use their monitoring results as inputs to determine whether their water contains a mixture of Index PFAS exceeding that level. *Id.*

Petitioners fail to explain how a Standard based on a hazard index does not establish a "level." They claim that a "level" must be expressed as the "concentration" of an individual substance in water. Utility Br. 34. But their own brief concedes that "level" has a broader meaning that includes any measure of "relative position or rank on a scale" or a "relative degree…[of] intensity." *Id.*; *accord* RANDOM HOUSE COLLEGE DICTIONARY 770 (Laurence Urdang et al. eds., 1973) (defining "level" as "a position in a graded scale of values; status; rank"). The hazard index is a scale measuring the relative intensity of the hazard presented, with a value above 1 representing amounts of the mixture at which there are known or anticipated adverse health effects and values at or below 1

representing amounts at which no such effects are expected. JA-[RTC_4-418_to_4-419].

Petitioners are wrong that all of EPA's other Standards are "expressed and described as a concentration level"; in fact, the example they cite disproves their argument. Utility Br. 34 (discussing Standards for radionuclides). The Standards for combined radium and for gross alpha particle radioactivity are each expressed in picocuries per liter. 40 C.F.R. § 141.66(b), (c). These units do not represent the *concentration* of any particular radionuclides in water, but rather the *intensity of radioactivity* in the water, measured via the rate of radioactive decay. *City of Waukesha*, 320 F.3d at 232 n.1; *see also* 51 Fed. Reg. 34836, 34850 (Sept. 30, 1986) (providing background on radionuclides and their measurement in advance notice of proposed rulemaking). Likewise, the Standard for beta particle and photon radioactivity is expressed in millirems per year, which measures the dose of radiation received over a set time period and accounts for both the quantity and energy of radiation present. 40 C.F.R. § 141.66(d); *City of Waukesha*, 320 F.3d at 232 n.2.

Like the hazard index, each of these Standards uses a metric other than the concentration of a contaminant in water to set the maximum permissible "level." Notably, EPA's reason for taking this approach with radionuclides is directly analogous to its reason for using a hazard index here: the need to "account for the

different potencies of the mixture components." JA-[RTC_4-429]; *see* 65 Fed. Reg. 76708, 76720 (Dec. 7, 2000) (explaining factors affecting hazards of various radionuclides). Because the mixture components are not equally hazardous and may occur in different proportions at different times and locations, a Standard set in the form of a total concentration of these components would not adequately protect against adverse health effects and would be over-protective in some cases and under-protective in others. JA-[RTC_4-430]. Petitioners' narrow reading of "level" would hamstring EPA's ability to address these kinds of mixtures.

Likewise, there is nothing "fundamentally different" about a Standard that "depends on the relative occurrence of four different contaminants in a sample of drinking water." Utility Br. 35. The same is true of *any* Standard that limits a contaminant as a group, like EPA's Standards for disinfection byproducts or radionuclides. 40 C.F.R. §§ 141.64(b), 141.66. For example, a system's compliance with the Standard for haloacetic acids will depend on "fluctuations in the relative concentrations of" the five acids collectively regulated by that Standard, Utility Br. 36, just as a system's compliance with the hazard index in this Rule will depend on the measured concentrations of different Index PFAS in its water. The only distinction here is that the concentrations of Index PFAS are given different weights before adding them together to reflect the lower potency of one component (PFBS) compared to the other Index PFAS. *See* JA-[RTC_4-368]

(noting for contaminants with dose-additive effects, overall risk depends on sum of individual contaminant concentrations "scaled for potency").

Nor is the hazard index made "fundamentally different" by use of a "mathematical equation" to determine compliance with the Standard. Utility Br. 35. Again, the mathematical steps involved in calculating the hazard index (division and addition of individual contaminant concentrations) are no different or more complex than the steps required for the many Standards for which compliance is based on a running annual average of quarterly sampling results. JA-[RTC_5-391]; *see* 40 C.F.R. §§ 141.23, 141.24, 141.26, 141.133. Thus, a Standard expressed as a hazard index is consistent with the Act and with EPA's past practice.

D. The Index PFAS Standard Appropriately Regulates Mixtures of Index PFAS.

Petitioners largely repackage arguments regarding the regulatory determination of the Index PFAS as arguments that the Standard is arbitrary and capricious. *Compare* Industry Br. 40-44 *with* Utility Br. 36-40; Pt.II.A.3. These arguments are no more availing regarding the Standard.

First, Petitioners assert the Index PFAS have different health effects. Utility Br. 36-38. As explained in Pt.II.A.3, *supra*, this is incorrect. Exposure to different Index PFAS elicit many similar adverse health effects, including effects on development, the liver, and kidney, and endocrine, respiratory, and reproductive

systems. JA-[FR_32552]; JA-[RTC_4-373_to_4-375, 4-424_to_4-429]; JA-[MCLG_1-7_to_1-10].

Second, Petitioners misstate the Board's recommendations regarding use of a hazard index. Contrary to Petitioners' assertion, Utility Br. 38-39, the Board never stated that a hazard index is "most appropriate" as a screening tool. JA-[SAB_Report]. EPA sought the Board's input on its original proposal to use a tiered approach to evaluate noncancer health risks associated with PFAS mixtures in which the hazard index could be used as the first tier before more data-intensive steps were taken. JA-[RTC_4-423_to_4-426]. The Board agreed that the hazard index was "a reasonable approach" for regulating PFAS mixtures because of their dose-additivity, but specifically recommended that EPA remove additional tiers of evaluation and use a simplified structure like the hazard index. JA-[SAB_Report_91, 110]; JA-[RTC_4-424]. Thus, far from criticizing this approach, the Board endorsed it.

Finally, Petitioners misrepresent the EPA guidance document they claim requires consistent proportions. Utility Br. 39-40. Petitioners conflate the concept of a mixture generally with a specific type of mixture *analysis* called the "whole-mixture" approach. JA-[Chem_Mix_Guidance_EPA-HQ-OW-2022-0114-0075_3]. As the guidance document explains, there are different methods of analyzing mixtures that include both "whole-mixture" approaches and component-

based approaches (like a hazard index). JA-[Chem_Mix_Guidance_3]. The references to similarities in proportions and components that Petitioners cite relate to one particular type of analysis under the "whole-mixture" approach, *not* a hazard-index approach. JA-[Chem_Mix_Guidance_10, 37-38]. Indeed, EPA explained that the variability of proportions of individual PFAS within the mixtures of the Index PFAS was the very reason it is using the hazard-index approach. JA-[Chem_Mix_Guidance_79-80]; JA-[RTC_4-420_to_4-421]. And although Petitioners quibble with EPA's use of the term "mixture" to describe combinations of Index PFAS because they claim the "common sense" definition of "mixture" requires "components and respective portions [that] exist in approximately the same pattern," Utility Br. 40, the longstanding definition of a mixture in chemistry is "an aggregate of two or more substances that are not chemically united and that exist *in no fixed proportion to each other*." *Mixture*, DICTIONARY.COM, *available at* https://www.dictionary.com/browse/mixture (emphasis added); *Mixture*, RANDOM HOUSE COLLEGE DICTIONARY 865 (Laurence Urdang et al. eds. 1973) (same).

Accordingly, EPA's decision to regulate the Index PFAS using a hazard-index methodology is reasonable and supported by record evidence.

E. The HFPO-DA Individual Standard Is Reasonable and Supported by the Record.

EPA thoroughly reviewed the scientific data to develop the HFPO-DA Goal and Standard. Petitioners challenge two inputs into the Goal: EPA's consideration of non-drinking water exposure to HFPO-DA (the "relative source contribution") and various aspects of the Toxicity Assessment. Neither of these arguments is availing.

1. EPA Reasonably Considered Non-Drinking Water Exposure to HFPO-DA.

To set a Goal at the level of HFPO-DA in drinking water at which "no known or adverse effects on the health of persons occur and which allows an adequate margin of safety," EPA must consider not only human exposure to HFPO-DA through drinking water, but also non-drinking water HFPO-DA exposure. JA-[MCLG_2-3, A-8_to_A-15]; JA-[RSC_Guide_EPA-HQ-OW-2022-0114-0882_1-5_to_1-8]. EPA does this through assessment of the "relative source contribution." 42 U.S.C. § 300g-1(b)(4); JA-[MCLG_2-3]; JA-[RSC_Guide_1-7_to_1-8]. EPA takes "a conservative approach to public health" by assuming 20% of exposure is from drinking water and 80% from other exposure sources "when adequate exposure data do not exist…." JA-[RSC_Guide_1-7]. Here, EPA fully evaluated the available peer-reviewed scientific studies and determined that inadequate data existed to calculate the specific amount of exposure to HFPO-DA

an individual would likely receive from each media. JA-[MCLG_2-3, A-8_to_A-15]. Thus, pursuant to EPA's longstanding methodology, EPA determined that a relative source contribution of 20% was appropriate. The Court affords EPA particular deference for its evaluation of this type of scientific data within its "technical expertise." *NYC C.L.A.S.H., Inc. v. Fudge*, 47 F.4th 757, 763 (D.C. Cir. 2022).

EPA thoroughly explained its consideration of peer-reviewed scientific studies—including all articles Petitioner Chemours provided—to determine whether HFPO-DA exposure may occur from non-drinking water sources. JA-[MCLG_A-8_to_A-15]; JA-[RTC_4-587_to_4-590]; *contra* Industry Br. 55. At the outset, much of what Petitioner Chemours provided was not valid scientific data or peer reviewed studies (*e.g.*, internal PowerPoint slides and public-service announcements) or failed to even reference HFPO-DA. JA-[RTC_4-587_to_4-590]. Nevertheless, EPA included a table in its response to comments specifically addressing each document submitted, confirming EPA considered the valid scientific studies therein, and explaining why each document that was not considered failed to meet the statutory standard for consideration. JA-[RTC_4-587_to_4-590]. Notably, Petitioners do not disagree with EPA's assessment of any of these documents. Industry Br. 54.

Contrary to Petitioners assertion, Industry Br. 56, EPA did not disregard data showing a lack of non-drinking water exposure routes. EPA fully discussed both studies that demonstrated HFPO-DA presence and studies that did not. JA-[MCLG_A-11_to_A-15]. Collectively, the studies demonstrated the presence of HFPO-DA in certain foods, but not in others. JA-[MCLG_A-11_to_A-12]. Studies also detected HFPO-DA in soil and sewage sludge, air emissions, rainwater, and indoor dust. JA-[MCLG_A-12_to_A-15]. EPA thus concluded that several studies showed people may be exposed to HFPO-DA through non-drinking water exposure routes. JA-[MCLG_A-11_to_A-15]. Critically, Petitioners identify no error in EPA's reliance on *any* of these studies. Industry Br. 55-56. And although Petitioners cite to an extra-record email regarding preliminary data on PFAS in dust that Petitioners claim EPA failed to consider, Industry Br. 56, the final results of that study merely document that, at the ten specific military bases studied, HFPO-DA overwhelmingly was not present in *any* form. *See* ATSDR Report at 57, https://www.atsdr.cdc.gov/pfas/docs/PFAS-EA-Final-Report-508.pdf. EPA thus reasonably concluded exposure may occur through non-drinking water sources.

EPA then explained that, because "the available information [on HFPO-DA exposure] is limited" and "does not allow for the quantitative characterization of the relative levels of exposure among these difference sources," EPA would follow

its standard methodology of applying a relative source contribution of 20%. JA-[MCLG_2-3, A-15]. EPA's protocol does not "strongly caution[] against" using a 20% value. *Contra* Industry Br. 55. It states that "[w]hen other sources or routes of exposure are anticipated but data are not adequate" to quantify the precise amount of exposure from drinking water versus other media, "there is an even greater need to make sure that public health protection is achieved," and "the 20 percent default will still generally be used." JA-[RSC_Guide_4-6]. Petitioners do not identify a single peer-reviewed scientific study that quantifies HFPO-DA exposure through drinking water as compared to other exposure media, nor do Petitioners offer any evidence to *specifically calculate* a relative source contribution value EPA should have used. *See generally* Industry Br. 54-57.

EPA's extensive discussion of the scientific literature of HFPO-DA exposure surpasses its obligation to consider all relevant factors and demonstrate a reasonable connection between the record facts and policy choice. *Sinclair Wyo.*, 101 F.4th at 882.

2. EPA Reasonably Relied on Rodent Studies Showing HFPO-DA Elicits a Constellation of Adverse Liver Effects Relevant to Humans.

EPA thoroughly analyzed the available scientific literature before relying on rodent studies to determine that a constellation of adverse liver effects is the most critical effect observed after HFPO-DA exposure to derive a Goal at "the level at

which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." JA-[MCLG_1-1, 2-1]. Although Petitioners disagree with EPA's reliance on these studies and conclusions, the record—including *multiple* rounds of independent expert peer reviews—overwhelmingly supports EPA's conclusions. JA-[HFPO-DA_TA_Appx_D]; JA-[HFPO-DA_1st_Peer_Review_13-31]; JA-[HFPO-DA_2nd_Peer_Review_10-15]. These factual findings are entitled to an "extreme degree of deference." *NYC C.L.A.S.H., Inc.* 47 F.4th at 763.

a. Petitioners incorrectly assert that *no* liver effects in rodents are relevant to humans. Industry Br. 57-60. But EPA's analysis is supported by peer-reviewed scientific literature and was affirmed by multiple rounds of external peer review by independent human health scientists.

Petitioners incorrectly assert all liver effects observed in rodents result from a toxicity pathway (or "mode of action") called PPAR-alpha, which they claim is not relevant to humans. Industry Br. 57-58. But there are multiple modes of action for liver effects in rodents other than PPAR-alpha, including the cytotoxic mode of action. JA-[RTC_4-517_to_4-520]. EPA identified scientific literature demonstrating that only a *decrease* in one type of liver cell death (apoptosis) is associated with PPAR-alpha, whereas other modes of action relevant to humans are associated with the specific liver effects at issue here—*increases* in apoptosis,

various types of necrosis, and increased serum liver enzyme concentrations, *i.e.*, a "constellation of liver effects"). JA-[RTC_4-516_to_4-521]; JA-[HFPO-DA_TA_29, 42-45, 51-54, 72-77, 82-90, Appx_D]; JA-[HFPO-DA_1st_Peer_Review_13-21]; JA-[Draft_HFPO-DA_TA_RTC_EPA-HQ-OW-2022-0114-3616_12-15, 34-35]; JA-[Resp_Chem_IQA_EPA-HQ-OW-2022-0114-3629_7-14]. Petitioners ignore EPA's cited studies, and instead erroneously assert EPA's analysis was based on "specula[tion]." Industry Br. 57.

Notably, EPA *twice* sought external peer review regarding whether the specific rodent studies relied upon were relevant to humans, and both panels unanimously agreed they were. JA-[HFPO-DA_1st_Peer_Review_17-21, 25-31]; JA-[HFPO-DA_2nd_Peer_Review_10-15]. And, when Petitioner Chemours previously challenged a specific type of liver cell death reported in studies EPA considered when determining HFPO-DA's toxicity to humans, EPA even convened a *third* group of independent experts, the Pathology Working Group at the National Institutes of Health, to conduct an independent analysis of the pathology slides from the studies. JA-[Draft_HFPO-DA_TA_RTC_11-15]; JA-[HFPO-DA_TA_Appx_D]. The Group generally supported the original study's findings, concluding that the pathology slide evaluations demonstrated a range of adverse liver effects, including increased single-cell necrosis, cytoplasmic alteration, focal necrosis, and apoptosis—collectively, a "constellation of

lesions"—that it identified as adverse effects observed after exposure to HFPO-DA. JA-[HFPO-DA_TA_D-22].

Although Petitioners now complain that the Group did not make any specific findings regarding the relevance of the constellation of lesions to humans, Industry Br. 59-60, Petitioners misunderstand the Group's role. The Group was asked to diagnose the liver effects using a particular type of liver diagnostic criteria (the "Elmore" criteria. JA-[HFPO-DA_TA_D-22]. Evaluation of whether a particular rodent effect can be extrapolated to humans follows an analysis of "the Hall criteria," which is conducted *after* identification of the specific liver effect. JA-[RTC_4-517]; JA-[FR_32548-49]. Two panels of experts also unanimously affirmed EPA's "Hall criteria" analysis. JA-[HFPO-DA_1st_Peer_Review_17-21, 25-31]; JA-[HFPO-DA_2nd_Peer_Review_10-15].

Thus, although Petitioners may disagree with EPA's scientific assessment, EPA's analysis and conclusions are supported by ample evidence in the record and are well-explained.

b. The record demonstrates that EPA appropriately considered the Chappell article Petitioner Chemours identified in its comments. Industry Br. 58; JA-[RTC_4-517_to_4-520].

First, EPA considered the Chappell article in conjunction with the other available scientific studies on this issue. JA-[HFPO-DA_TA_76-77]. EPA

determined, in its technical expertise, that the weight of evidence supported the human relevance of the liver effects resulting from HFPO-DA exposure. JA-[HFPO-DA_TA_76-77]; JA-[RTC_4-517_to_4-520]; JA-[Resp_Chem_IQA_8]. For example, although the Chappell study did not find necrosis in the slides studied, the seven pathologists in the Pathology Working Group analyzed the same slides and found necrosis in addition to apoptosis. JA-[HFPO-DA_TA_D-20_to_D-21_Tbl._1]. Although Petitioners may disagree with EPA's weighing of this evidence, this Court affords EPA's evaluation of within its technical expertise particular deference. *Huntsman Petrochem.*, 114 F.4th at 735.

Second, Petitioners are incorrect that the Chappell study concluded that *no* modes of action other than PPAR-alpha are at issue in *any* liver effects resulting from HFPO-DA exposure. Industry Br. 58. The article did not address all other potential modes of action, including the cytotoxic mode of action, and thus cannot refute the potential applicability of other modes of action. JA-[Chappell_study_EPA-HQ-OW-2022-0114-3431_505-06]; JA-[RTC_4-518_4-519].

Finally, EPA explained that Chappell's finding of apoptosis is consistent with other studies that demonstrate that apoptosis is part of the constellation of liver effects seen in response to HFPO-DA exposure. JA-[RTC_4-519_to_4-520]. EPA thus fully considered the Chappell study.

3. EPA Reasonably Applied Both Subchronic-to-Chronic and Database Uncertainty Factors of 10.

When deriving a Goal and Standard, EPA must first determine the reference dose (an estimate of daily oral exposure that is "likely to be without an appreciable risk of deleterious effects during a lifetime") by analyzing the scientific literature and applying certain "uncertainty factors." JA-[Reference_Dose_Protocol_EPA-HQ-OW-2022-0114-0100_G-7, 4-40_to_4-41]. Uncertainty factors are numerical values of 1, 3, or 10 that account for gaps or uncertainties in the available scientific data for the chemical. JA-[Reference_Dose_Protocol_4-40_to_4-41]. Because of gaps in the scientific studies conducted on HFPO-DA at the time of the rulemaking, EPA reasonably set both the subchronic-to-chronic and database uncertainty factors in its derivation of the HFPO-DA chronic reference dose at 10.

First, EPA's guidance regarding application of uncertainty factors to chronic reference doses explains that a "default value of 10 for [the subchronic-to-chronic uncertainty factor] is applied…on the assumption that effects from a given compound in a subchronic study occur at a 10-fold higher concentration than in a corresponding (but absent) chronic study." JA-[Reference_Dose_Protocol_4-45_to_4-46]. Although EPA originally set this value at 3 when drafting its initial toxicity assessment in 2018, additional studies became available that indicated studies of longer duration were needed. JA-[HFPO-DA_TA_92-93]. Contrary to

Petitioners' assertion, Industry Br. 53-54,[13] EPA fully explained the reasons for this increase. JA-[HFPO-DA_TA_41-45, 92-93]; JA-[HFPO-DA_2nd_Peer_Review_10]. Specifically, based on the Pathology Working Group's reanalysis of pathology slides, EPA revised its assessment of the most sensitive population from parental males to lactating females. JA-[HFPO-DA_TA_41-45, 92-93]; JA-[HFPO-DA_2nd_Peer_Review_10]; JA-[HFPO-DA_Draft_TA_EPA-HQ-OW-2022-0114-0521_60]. EPA explained that female test subjects had been exposed to HFPO-DA for a shorter duration than the exposure duration for males, thus requiring an increase in the subchronic-to-chronic uncertainty factor. JA-[HFPO-DA_TA_92-93]; JA-[HFPO-DA_2nd_Peer_Review_20]. Additionally, because the available studies demonstrated female rodents had progressing liver effects over longer durations of exposure to HFPO-DA, EPA explained it was "critical to have a 2-year chronic study in the mouse to understand the progression of these liver effects," but no such studies existed. JA-[HFPO-DA_TA_93].

[13] EPA had no heightened burden to "supply a reasoned analysis," Industry Br. 54 (quoting *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 57 (1983)), for revising this uncertainty factor between the draft and final toxicity assessment in response to public comment and updated scientific studies. *State Farm* refers to an agency "changing its course" by revising a final regulation, not a draft scientific assessment. *State Farm*, 463 U.S. at 57.

Second, Petitioners question why EPA increased its database uncertainty factor from 3 to 10 in response to additional studies and findings. Industry Br. 52-53. But EPA explained that scientific papers published after the draft assessment identified new health effects needing more study—specifically, reproductive, developmental, and neurotoxic effects. JA-[HFPO-DA_TA_93-96]; JA-[HFPO-DA_2nd_Peer_Review_15]; JA-[Draft_HFPO-DA_TA_RTC_23-24]. For example, one study observed placental lesions in pregnant mice following exposure to higher doses of HFPO-DA, and EPA explained that additional studies were needed both at lower doses and to determine how those lesions "might impact reproductive and developmental outcomes." JA-[HFPO-DA_TA_94]. Similarly, three studies published after the draft toxicity assessment showed alterations in thyroid hormones in pregnant subjects after gestational exposure to HFPO-DA, but EPA explained the potential neurodevelopmental effects that might result from the thyroid hormone effects required additional investigation at lower doses. JA-[HFPO-DA_TA_96]. Thus, contrary to Petitioners' assertion, Industry Br. 52-53, EPA specifically identified the critical data gaps it had discovered between the draft and final toxicity assessments. JA-[HFPO-DA_TA_93-96].

Third, EPA's proposal to increase both the subchronic-to-chronic and database uncertainty factors from 3 to 10 was supported by a panel of independent experts. JA-[HFPO-DA_2nd_Peer_Review_15-24].

Accordingly, EPA considered the "relevant factors" and articulated a "reasonable connection" between the facts found and the choice made. *Sinclair Wyo.*, 101 F.4th at 882.

F. EPA Satisfied Its Procedural Requirements for Consultation with the Science Advisory Board.

EPA sought the Board's comments on the key scientific issues involved in its regulations for these contaminants and addressed the Board's recommendations in its proposed and final Rule. JA-[FR_32729-31]. The Act does not require more. And ultimately, any procedural deficiencies in EPA's consultation with the Board would constitute harmless error that does not warrant any remedy—certainly not "vacating the Rule" in its entirety. Industry Br. 39.

The Act requires EPA to "request comments from the Science Advisory Board…prior to proposal of a [Goal] and [Standard]." 42 U.S.C. § 300g-1(e). Other than specifying when EPA must solicit comment, this broad language leaves EPA significant discretion regarding how and on what issues to seek the Board's input prior to proposal. Contrary to Petitioners' suggestion, SDWA does not require EPA to submit the specific Goals and Standards it proposes for the Board's

review.[14] Industry Br. 39. If Congress had intended to require as much, it would have done so explicitly.

That it did not is unsurprising. The Board exists only to provide "scientific advice" to EPA. 42 U.S.C. § 4365(a). EPA's selection of a specific Goal and Standard for a contaminant involves policy questions (including what constitutes an "adequate margin of safety" and what level is "feasible") that the Board is neither authorized nor qualified to address. *See id.* § 300g-1(b)(4). Moreover, requiring EPA to solicit the Board's comment on the specific Goal and Standard it proposes would be impractical, as it could trap EPA in a feedback loop of continuous consultation. EPA would have to go back to the Board for further comment each time it changes its proposed rules, even if it were changing the proposal in response to the Board's feedback. JA-[RTC_4-427].

In practice, EPA considers hundreds of scientific issues for any given regulation under the Act, and EPA must focus its consultation with the Board on the most important or novel issues.[15] *Id.* Here, EPA identified the most critical

[14] Petitioners appear to recognize as much: they do not challenge EPA's consultation with the Board regarding PFOS or PFOA, notwithstanding that EPA also did not solicit the Board's comments on those specific Goals or Standards. Industry Br. 38.

[15] *See, e.g.*, 86 Fed. Reg. 4198, 4276 (Jan. 15, 2021) (describing issues for which EPA sought Board comment on lead and copper Standards); 78 Fed. Reg. 10270, 10341 (Feb. 13, 2013) (total coliform Standard); 66 Fed. Reg. 45676 (Aug. 29, 2001) (Standards for microbial pathogens, disinfectants, and disinfection byproducts).

scientific issues to its forthcoming proposals that had not yet undergone peer review, where Board commentary would be most valuable. *Id.* EPA submitted questions to the Board on these issues, including dose-additivity and the reasonableness of using a hazard index or other methods for assessing risks of PFAS mixtures. *Id.*; *see* JA-[Response_to_Final_SAB_Recommendations_EPA-HQ-OW-2022-0114-0043_at_46-71]. The Board met on four occasions to deliberate on these charge questions and others EPA submitted for this rulemaking; published a draft report; considered oral and written public comments; and provided numerous recommendations to EPA. JA-[RTC_4-426]. EPA considered these recommendations and included its responses to the Board in its proposed and final Rule. *Id.* The Act does not require more.

Finally, even if the Court agrees with Petitioners, any procedural violation was harmless error. *See City of Waukesha*, 320 F.3d at 246. Petitioners do not claim to have suffered any prejudice from EPA's alleged failure to consult with the Board and do not show further consultation would have altered or improved anything about the Rule—particularly given that EPA accepted all of the Board's recommendations with respect to PFAS mixtures. JA-[Response_to_Final_SAB_Recommendations_at_12, 46-71]. Moreover, while Congress may have considered Board consultation a worthwhile effort, it clearly did not intend this requirement to be essential. The Act does not even require the

Board to respond to EPA's solicitation, and it prohibits EPA from delaying final promulgation of a Standard to allow for Board consultation. 42 U.S.C. § 300g-1(e).

IV. EPA Appropriately Considered Costs and Benefits in Promulgating the Rule.

Petitioners' challenges to EPA's consideration of costs and benefits in the Rule fail for numerous reasons. First, Petitioners' assertion that what is "feasible" under SDWA depends on a balance of costs and benefits is wrong as a matter of law. Second, the Act does not permit judicial review of EPA's separate determination that the Rule's benefits justify its costs. Third, to the extent it is reviewable here, EPA's determination was reasonable because it properly considered the Rule's substantial nonquantifiable benefits, considered certain Standards' impacts collectively to accurately account for their overlapping costs and benefits, and addressed each of Petitioners' objections on the record. Finally, if the Court agrees with Petitioners on any issue, vacatur of the Rule is inappropriate.

A. EPA's Selection of "Feasible" Standards Does Not Depend on Comparison of Costs and Benefits.

Petitioners' arguments challenging the Standards based on purported deficiencies in the Economic Analysis rely on a fundamentally mistaken proposition: that in order to set a Standard that is as close to the Goal as

"feasible," EPA must strike some particular balance between the Standard's benefits and costs. *See* Utility Br. 2, 53-57; Industry Br. 6, 14-23. Petitioners improperly conflate EPA's analysis of what Standard is "feasible" under subparagraph (b)(4)(B) with its separate determination of whether such a Standard's benefits justify its costs under subparagraph (b)(4)(C). As this Court already held in *City of Portland*, SDWA's text, structure, and legislative history confirm that these analyses are distinct and that whether a Standard is "feasible" does not turn on its relative benefits and costs. 507 F.3d at 712.

The text and structure of the Act make clear that subparagraphs (b)(4)(B) and (b)(4)(C) involve different analyses based on different factors. Subparagraph (b)(4)(B) directs EPA to set a contaminant's Standard as close as "feasible" to its health-protective Goal. 42 U.S.C. § 300g-1(b)(4)(B). This analysis focuses on the availability and performance of the best available technology for treating a contaminant. JA-[FR_32573]. Although EPA's evaluation of what is "feasible" also involves some "consideration" of cost, *see* 42 U.S.C. § 300g-1(b)(4)(D), that consideration is limited to whether the costs of compliance are *affordable* for large public water systems and does not seek to balance costs against benefits. *City of Portland*, 507 F.3d at 712; JA-[FR_32573].

By contrast, subparagraph (b)(4)(C) explicitly directs EPA to determine whether the benefits of a Standard set pursuant to (b)(4)(B) justify its costs based

on the results of an Economic Analysis conducted specifically for that purpose. 42 U.S.C. § 300g-1(b)(4)(C). EPA's determination under subparagraph (b)(4)(C) does not alter or influence its determination of what Standard is as close to the Goal as feasible under (b)(4)(B). Instead, it is the first step in a separate process through which EPA "may" decide (in its discretion) to promulgate a Standard that is *not* as close to the Goal as feasible. *See* 42 U.S.C. § 300g-1(b)(6).

Specifically, if EPA finds the benefits of a Standard set pursuant to subparagraph (b)(4)(B) justify the costs, then it cannot depart from that process, even if a Standard set at a different level might have greater net benefits. But if EPA determines the benefits do not justify the costs, it "may" promulgate a less stringent Standard at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." *Id.* § 300g-1(b)(6)(A). This is the only circumstance in which SDWA authorizes EPA to set a contaminant's Standard based on its evaluation of the relative costs and benefits.

EPA's interpretation that "feasible" does not require comparing costs and benefits is not only the best reading of the Act, it is the *only* reading that is consistent with this statutory framework. Paragraph (b)(6) offers a discretionary release valve allowing EPA to depart from the Act's normal Standard-setting requirements where they result in Standards that are not justified by their benefits. If determining "feasibility" already required balancing costs and benefits, this

release valve would be unnecessary: any Standard for which benefits did not justify costs would by definition be infeasible and would have to be adjusted upward under subparagraph (b)(4)(B) until the benefits justified the costs, without any need to resort to the provisions of paragraph (b)(6). Thus, Petitioners' interpretation would read paragraph (b)(6)—one of the most prominent changes included in Congress's 1996 amendments to SDWA—out of the statute.

This Court has already squarely rejected Petitioners' reading of the feasibility requirement for precisely these reasons. In *City of Portland*, petitioners claimed that alleged errors in EPA's Economic Analysis under subparagraph (b)(3)(C) undermined EPA's determination that the challenged Standard was feasible. 507 F.3d at 712. The petitioners argued that a Standard "is only 'feasible' if its benefits outweigh its costs." *Id.* This Court disagreed, noting that "when Congress wanted EPA to undertake cost-benefit analysis, it said so expressly." *Id.* Likewise, if "feasible meant that the [Standard's] benefits justified its costs," then the release valve offered by paragraph (b)(6) "would be surplusage." *Id.* The Court concluded that feasibility does not require balancing costs against benefits and simply means "technically possible and affordable." *Id.*

Finally, the legislative history confirms this Court's and EPA's reading of the statute. The Senate Committee's report discussed feasibility as a separate concept from comparison of costs and benefits, noting that paragraph (b)(6) would

give EPA "discretionary authority to establish less stringent standards (than *feasible*), when the Administrator determines that the benefits of a [Standard] set at the *feasible level* would not justify the costs …." S. Rep. 104-169, at 31 (emphases added). That report also emphasized that EPA could still choose to set the Standard for a contaminant as close to its Goal as feasible, "even if the Administrator determines that the benefits of the [Standard] at this level do not justify the costs"—a choice that would be impossible if determining feasibility itself required a finding that benefits justify costs. *Id.* at 33. And the House Committee's report noted that the 1996 amendments would "retain[] the basic standard setting process" from earlier iterations of the Act, indicating that neither the cost-justification determination in subparagraph (b)(4)(C) nor the requirement to conduct an Economic Analysis in subparagraph (b)(3)(C) were intended to change how EPA determined feasibility under subparagraph (b)(4)(B). H.R. Rep. No. 104-632, at 27 (1996).

Petitioners' interpretation of the feasibility requirement is incompatible with the statute and foreclosed by *City of Portland*. Accordingly, the Court should reject their arguments.

B. The Act Precludes Judicial Review of EPA's Finding That the Rule's Benefits Justify Its Costs.

Because feasibility under SDWA does not involve comparison of a Standard's costs and benefits, Petitioners' challenges to the Economic Analysis can

only be relevant to the merits of EPA's separate determination under Section 300g-1(b)(4)(C). But the Act does not permit judicial review of that determination where, as here, EPA sets the Standard for a contaminant as close to its Goal as feasible. Instead, judicial review is only available where EPA exercises its discretion to adopt an alternative Standard that is less stringent than otherwise required.

SDWA separately addresses judicial review of EPA's cost-justification determinations. It states that EPA's determination as to whether the benefits of a Standard justify its costs "shall be reviewed by the court pursuant to section 300j-7…*only* as part of a review of a final [Standard] that has been promulgated *based on the determination*." 42 U.S.C. § 300g-1(b)(6)(D) (emphases added). Those circumstances are not presented here.

The only Standards that are "promulgated based on" such a determination are those set under subparagraph (b)(6)(A) at a level less stringent than what is feasible. Standards under subparagraph (b)(6)(A) are "based on" EPA's determination regarding costs and benefits because in order to promulgate such Standards, EPA must first determine that the benefits of a Standard at the feasible level "would not justify" the costs. 42 U.S.C. § 300g-1(b)(6)(A). And in order to select the appropriate alternative Standard under this provision, EPA must also

affirmatively determine whether the benefits of its chosen alternative *do* justify the costs. *Id.*

By contrast, a Standard that is set pursuant to subparagraph (b)(4)(B) (*i.e.*, as close to the Goal as feasible) is not one that has been promulgated "based on the determination" of whether its benefits justify the costs. This is evident from the fact that under SDWA's plain text, EPA may set the Standard as close to the Goal as feasible *regardless of the outcome* of its assessment of benefits and costs under subparagraph (b)(4)(C). If EPA finds the benefits of a Standard at the feasible level justify the costs, it must proceed to set the Standard as close to the Goal as feasible. But even if it finds the benefits *do not* justify the costs, the statutory text leaves EPA with discretion to set the Standard at the feasible level. 42 U.S.C. § 300g-1(b)(6)(A) (stating EPA "may" promulgate alternative Standard if benefits do not justify costs); *see also* S. Rep. No. 104-169, at 33 (stating EPA "is not precluded from using the authority of section 1412(b)(4)" to set Standard at the feasible level, "even if the Administrator determines that the benefits of the [Standard] at this level do not justify the costs"). Either way, EPA's choice of the Standard under subparagraph (b)(4)(B) is not and cannot be "based on" its determination whether benefits justify costs.

EPA's interpretation represents the best reading of the statute. It is supported by the text discussed above and the statutory framework, which notably

situates this provision addressing judicial review of EPA's cost-benefit determination within the provisions granting EPA limited discretionary authority to promulgate alternative Standards based on that determination. In fact, the existence of this provision alone is telling: if Congress had meant to authorize judicial review of *every* cost-benefit determination EPA makes in promulgating a Standard, it would not have needed to insert a special judicial-review provision specifying when such review is available at all.

EPA's interpretation is also consistent with the legislative history of SDWA's 1996 amendments, which demonstrates that Congress intended EPA's choice of whether to exercise its authority under paragraph (b)(6) to be "entirely discretionary." S. Rep. No. 104-169, at 35. The Senate Committee's report emphasized that even where EPA finds the benefits of a Standard at the feasible level do not justify the costs, "[n]o court may compel the Administrator to set a standard using the authority of" paragraph (b)(6). *Id.* Allowing judicial review of EPA's cost-benefit determination for every rulemaking under the Act would undermine Congress's grant of broad discretion to EPA to adopt a Standard that is as close to the corresponding Goal as feasible regardless of whether the benefits justify the costs.

Accordingly, Section 300g-1(b)(6)(D) precludes this Court from reviewing EPA's determination that the benefits of this Rule's Standards justify their costs.

C. EPA Reasonably Determined that the Rule's Benefits Justify Its Costs.

To the extent judicial review is permitted here, EPA's determination that the benefits of the Standards justify their costs is not arbitrary or capricious. As indicated by the term "justify," SDWA grants EPA significant discretion regarding how to make such a determination for a Standard, and this Court's review is limited to examining whether EPA failed to consider a relevant factor. EPA properly considered the quantifiable and nonquantifiable costs and benefits of the Standards, supported its determination in the record with a robust Economic Analysis, and adequately responded to each of the objections Petitioners raise below.

1. To the Extent the Court May Review EPA's Assessment of Costs and Benefits, The Scope Is Limited to Arbitrary-and-Capricious Review.

If the Court concludes it may review EPA's cost-justification determination under subparagraph (b)(4)(C), it may not set aside EPA's determination "unless the court finds that the determination is arbitrary and capricious." 42 U.S.C. § 300g-1(b)(6)(D). This standard of review is highly deferential and focuses on whether EPA "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible

that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43.

SDWA does not require EPA to use any particular metric for determining whether a Standard's benefits "justify" its costs, such as evaluating whether the benefits "outweigh" the costs or whether less stringent Standards would yield higher net benefits. *Contra* Industry Br. 6, 17; Utility Br. 56. To the contrary, Congress understood that the term "justify" does not mean "exceed" or "outweigh," and nothing in the Act requires EPA to "demonstrate that the dollar value of the benefits are greater (or lesser) than the dollar value of the costs." S. Rep. No. 104-169, at 33. Even where EPA exercises its discretion under paragraph (b)(6) to promulgate less stringent Standards, the Act still does not require EPA to set those Standards at a level that provides greater benefits than costs or otherwise maximizes net benefits. *See* 42 U.S.C. § 300g-1(b)(6)(A) (stating alternative Standard must "maximize[] health risk reduction benefits at a cost that is justified by the benefits").

In the absence of specific instructions from Congress, EPA has discretion regarding how to determine whether a Standard's benefits justify its costs. *See Michigan v. EPA*, 576 U.S. 743, 759 (2015) (stating that where statute requires consideration of cost, it is "up to the Agency to decide (as always, within the limits of reasonable interpretation) *how* to account for cost") (emphasis added). Where

(as here) the Court reviews EPA's cost-benefit determination for arbitrariness, the Court may not "substitute its judgment for that of the agency" and must cabin its review to whether EPA "examined the relevant data and has articulated an adequate explanation for its action." *State Farm*, 463 U.S. at 43; *Int'l Fabricare*, 972 F.2d at 389.

2. EPA Properly Based Its Determination on Both the Quantified and Nonquantifiable Costs and Benefits.

In preparing its Economic Analysis under Section 300g-1(b)(3)(C), EPA must consider all the "quantifiable and nonquantifiable" health risk-reduction benefits and costs of its Standards for which there is a "factual basis in the rulemaking record to conclude that such [benefits and costs] are likely to occur." 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(III). Here, EPA developed a robust, well-supported Economic Analysis that assessed these factors, along with all of the other factors required under subparagraph (b)(3)(C), and determined that the benefits of the Rule's Standards justify their costs. *See* JA-[FR_32633-718].

EPA concluded that the Rule's quantified benefits alone not only justified its costs, but slightly *exceeded* them. *See* JA-[FR_32709_Tbl.68] (identifying expected total net benefits of $760,000 annually). But as the Act requires, EPA proceeded to also consider the Rule's nonquantifiable benefits and costs. *See* JA-[FR_32715_Tbl.73] (summarizing costs and benefits EPA considered and whether each was quantified or nonquantifiable).

EPA described the nonquantifiable health benefits that were expected to result from reductions in PFOS and PFOA exposure and the record evidence supporting EPA's conclusion that they are likely to occur, including benefits associated with reductions in developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. JA-[FR_32696-700]; *see also* JA-[FR_32543-52] (describing evidence of adverse health effects from regulated PFAS). EPA also described the nonquantifiable health benefits it expected from the Rule's reductions in Index PFAS (as well as other unregulated PFAS that would be captured by treatment technologies through co-removal), including reductions in many of the same health effects. JA-[FR_32700-02]. EPA summarized additional nonquantifiable costs associated with the Rule. JA-[FR_32713]. Finally, EPA explained how each category of nonquantifiable costs or benefits was likely to impact the Rule's overall costs and benefits. JA-[FR_32714_Tbl.72].

Notably, EPA found based on the evidence available that "the nonquantifiable human health benefits associated with reductions in drinking water PFAS exposure are substantial and may reasonably exceed the benefits the agency was able to quantify for this final rule." JA-[Economic_Analysis_EPA-HQ-OW-2022-0114-3084_1-3]. Based on this analysis, along with EPA's consideration of costs (both quantified and nonquantifiable) and quantified benefits, EPA

reaffirmed its determination from the proposed rule that the benefits of the Rule justify its costs. JA-[FR_32716].

While Petitioners dispute several aspects of EPA's determination, many of their arguments are premised on discounting or completely ignoring the Rule's significant nonquantifiable benefits. *See, e.g.*, Industry Br. 17 (claiming Standards for Index PFAS are "not justified" based solely on net quantified benefits of those Standards). Petitioners do not dispute that EPA must account for nonquantifiable benefits in its Economic Analysis under subparagraph (b)(3)(C). *Id.* at 20. Instead, they argue that EPA was not allowed to consider any of the benefits it relied on because the term "nonquantifiable" does not include benefits that "*can* be measured but as to which the agency lacks sufficient evidence or data to make an adequately supported measurement." *Id.* at 21.

This argument fails for several reasons. As a threshold matter, Petitioners have waived this issue because they did not raise it in their comments on the proposed Rule. "It is black-letter administrative law that absent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue." *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001) (cleaned up). By failing to raise this issue during the comment period, Petitioners denied EPA the opportunity to articulate its response in the final Rule, including by explaining in the record how a

finding that these benefits are not truly "nonquantifiable" would impact EPA's determination of whether the Rule's benefits justify its costs. Accordingly, Petitioners are precluded from advancing this argument here.

In any event, EPA did not err by treating benefits it was unable to quantify due to data limitations as "nonquantifiable" benefits. Petitioners' sole support for their cramped statutory interpretation is to point out that the dictionary defines "nonquantifiable" as "not capable of being quantified." Industry Br. 21. Even taken at face value, this argument gets Petitioners nowhere. Both the cited definition and the Act are agnostic as to the *reasons why* a "nonquantifiable" benefit might not be "capable of being quantified." Some benefits or costs may be nonquantifiable because they "by their nature cannot be measured," *id.*; others are not "capable of being quantified" because the information necessary to accurately quantify them simply does not exist, is inaccessible to EPA, or would be impractical to develop.

Petitioners' definition of "nonquantifiable" costs and benefits is also inconsistent with the rest of the Act. The Economic Analysis provision requires EPA to consider all benefits and costs "for which there is a factual basis in the rulemaking record to conclude that [they] are likely to occur." 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(III). Many rulemakings involve benefits and costs that are expected to occur (or in some cases, are *certain* to occur), and that might

conceivably be measurable, but for which the data necessary to quantify their impacts is unavailable. Petitioners' reading of the Act would place EPA in an impossible position: it would have to either exclude these impacts from its Economic Analysis, violating its duty to consider all costs and benefits "for which there is a factual basis in the rulemaking record," *id.*; or else devote extensive time and resources to developing the information necessary to quantify these impacts, needlessly delaying its efforts to protect public health.

Congress did not require EPA to wait until it has perfect information before acting to address contaminants in drinking water. Indeed, the Act's provisions governing the Economic Analysis explicitly recognize that gaps may exist in EPA's knowledge and direct EPA to account for those gaps by considering "the quality and extent of the information" available and "the uncertainties in the analysis." 42 U.S.C. § 300g-1(b)(3)(C)(i)(VII). Likewise, the Act requires EPA to carry out its Standard-setting functions using "the best *available*, peer-reviewed science and supporting studies," not to affirmatively develop new information that is not already available. *Id.* § 300g-1(b)(3)(A) (emphasis added). This Court has generally recognized that agencies have "wide latitude in determining the extent of data-gathering necessary to solve a problem." *NRDC v. EPA*, 529 F.3d 1077, 1086 (D.C. Cir. 2008); *see Nat'l Ass'n for Surface Finishing v. EPA*, 795 F.3d 1, 12-13 (D.C. Cir. 2015) (finding EPA did not act arbitrarily by proceeding with the best

data available to it). Consistent with that precedent, the Court should not adopt an interpretation of "nonquantifiable" that would effectively freeze EPA by bogging it down in an endless cycle of data-gathering and read the term "nonquantifiable" out of the Act.

Industry Petitioners also question whether the nonquantifiable benefits EPA relied on will materialize, cherry-picking various phrases from the Rule and presenting them out of context to suggest that these benefits reflect "pure guesswork." Industry Br. 22-23. But Petitioners do not address the extensive supporting evidence EPA gathered in the record substantiating these benefits. EPA conducted a systematic review of the scientific literature regarding the health effects of PFAS, which provided evidence linking exposure to these contaminants with a broad range of adverse health outcomes. *See* JA-[FR_32696-702] (summarizing results of literature review). This effort more than satisfied EPA's requirement to support any nonquantifiable benefits with "a factual basis in the rulemaking record to conclude that such benefits are likely to occur." 42 U.S.C. § 300g-1(b)(3)(C)(i)(I).

3. EPA Was Not Required to Conduct a Stand-Alone Economic Analysis for Each Individual Standard in the Rule.

EPA did not err by considering the impacts of some portions of the Rule together with one another. Industry Br. 15-18. The benefits and costs of the

Rule's various Standards are highly interrelated, and the best interpretation of the Act is one that authorizes EPA to meaningfully analyze them.

As an initial matter, EPA did not "lump[] substances together into a single cost-benefit analysis." Industry Br. 15. EPA used contaminant-specific information to analyze the Rule's costs and benefits, permitting comparison of some Standards' incremental costs and benefits on a more granular level than for the entire Rule. For example, while EPA did not *individually* assess the costs and benefits of the Rule's Standards for PFOS and PFOA, EPA did evaluate the costs and benefits of promulgating those two Standards without the Rule's other Standards, and EPA found that their benefits justify the costs. JA-[RTC_13-513_to_13-514]; *see* JA-[FR_32710_Tbl.69] (summarizing costs and benefits of PFOS/PFOA Standards alone). EPA also evaluated the costs and benefits of adopting the PFHxS Standard on top of the PFOS and PFOA Standards, and determined that the benefits of this grouping justified the costs as well. JA-[RTC_13-514]. Finally, EPA considered the incremental impact on costs and benefits from adopting each of the other Index PFAS Standards (for PFNA, HFPO-DA, and mixtures of Index PFAS) and again found that the benefits justify costs for any grouping of these Standards and the PFOS/PFOA Standards.[16] *Id.*

[16] While Petitioners cite the Index PFAS Standards to illustrate how EPA's approach purportedly "obscur[ed]" some unjustified requirements, it is their own

EPA also explained in the record its reasons for evaluating the costs and benefits of the Rule's various Standards in this manner. Specifically, many characteristics of the regulated PFAS make it difficult to accurately evaluate the costs and benefits of regulating one contaminant in isolation from the others, including their tendency to co-occur, the dose-additivity of the Index PFAS, and the shared health impacts of many of these PFAS. JA-[RTC_13-513]. Notably, Standard-specific analyses would significantly overestimate the treatment costs of each Standard because they would fail to account for the cost efficiencies afforded by co-removal of the other regulated PFAS. *Id.* Finally, EPA explained that because it had already finalized a regulatory determination for PFOS and PFOA prior to this Rule, it was already obligated to promulgate Standards for those contaminants and any regulatory scenario considered in the Economic Analysis would need to account for the existence of Standards for both. *See* JA-[RTC_13-352, 13-513].

EPA's approach to evaluating the costs and benefits of the Standards promulgated in this Rule is permitted under SDWA. Nothing in the statute requires EPA to conduct a separate analysis for each individual Standard. Both subparagraph (b)(3)(C) (regarding the Economic Analysis) and subparagraph

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analysis that "obscures" the true benefits of these Standards by failing to account for any nonquantifiable benefits. Industry Br. 17.

(b)(4)(C) (regarding EPA's determination of whether benefits justify costs) speak in terms of what EPA must do when proposing a "national primary drinking water regulation." SDWA itself recognizes that a single national primary drinking water regulation may specify Standards for multiple contaminants simultaneously. 42 U.S.C. § 300f(1) (defining term as a regulation that "specifies *contaminants* which" may have adverse health effects and specifies a Standard for "*each* such contaminant") (emphasis added); *see* JA-[RTC_13-352] (noting PFOS/PFOA Standards are "not two 'separate regulations'" but "two [Standards] included in one regulation").

While subparagraphs (b)(3)(C) and (b)(4)(C) spell out the analyses EPA must conduct for "each" Standard that is contained within a national primary drinking water regulation, neither provision requires that EPA conduct those analyses in isolation for each Standard.[17] Instead, EPA may "publish, seek public comment on, and use" a single Economic Analysis so long as it analyzes all seven of the statutory factors for each Standard contained within the rule. 42 U.S.C. § 300g-1(b)(3)(C)(i).

Petitioners' alternative reading would unnecessarily constrain EPA's discretion over how to analyze the costs and benefits of its regulations without

[17] This Court has previously declined to read SDWA strictly as requiring EPA to analyze the costs and benefits of "each" Standard included in a rule. *See City of Waukesha*, 320 F.3d at 245.

promoting the Act's overall goals. For regulations like this one, in which the contaminants involved have strong co-occurrence, co-removal, dose-additivity, and shared health effects, disentangling the costs and benefits of one contaminant's Standard from another would be impractical. Moreover, it would likely yield misleading results. For example, analyzing one of the Rule's Standards in isolation would necessarily overestimate its treatment costs because it would fail to account for the sunk costs and economies of scale associated with co-treatment of that contaminant at systems that are already required to install treatment systems to address other PFAS. *See* JA-[RTC_13-513]. And because the regulated PFAS are co-removed by treatment processes, assessing benefits for each Standard separately would likely either overestimate the expected benefits (by double-counting them as attributable to each Standard) or underestimate them (by excluding benefits from co-removal), either of which would be inconsistent with Congress's desire for an accurate accounting of the Standards' benefits. *See* 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(II). Considering the Rule's impacts in a holistic manner allows EPA to more accurately evaluate the costs and benefits to make an informed determination on whether they are justified.

4. EPA Addressed Petitioners' Specific Concerns with the Economic Analysis in the Record.

Petitioners claim that EPA failed to respond to various objections that they raised regarding the Rule's Economic Analysis. To the contrary, EPA considered

each of Petitioners' concerns and addressed each of them in the administrative record. Because EPA adequately responded to these comments, its Economic Analysis was not arbitrary or capricious.

First, EPA responded to Petitioners' comments asserting it had underestimated the costs of compliance with the Standards based on a cost modeling report (the "Black & Veatch Study"), case studies, and other information they submitted to EPA. Utility Br. 54. Regarding the use of "older studies that do not account for inflation," Utility Br. 54, EPA responded to Petitioners' comments by adjusting its cost inputs to reflect the most recent data. EPA updated its equipment costs to 2022 dollars, collected new price quotes from vendors for cost driver equipment components, and made other adjustments to its cost model. JA-[FR_32645]; JA-[RTC_13-117, 13-217].

With respect to the Black & Veatch Study, EPA provided a detailed explanation of its areas of disagreement on the methodologies and assumptions used to develop that study's cost model. JA-[FR_32642-47_Tbls._24-26]; JA-[RTC_13-119_to_13-123]. EPA identified numerous assumptions in that report regarding the systems expected to require treatment, the capital costs of treatment technology, and operation and maintenance costs that compounded to significantly overestimate the compliance costs of this Rule's Standards. Notably, when applied to the case studies submitted with Utility Petitioners' comments, the Black &

Veatch Study's model overestimated the costs 88 percent of the time. *See* JA-[FR_32645]. By contrast, when EPA compared its own cost model's results to the costs of treatment technology packages supplied by a vendor of these systems, its results generally fell within 10 percent of the vendor costs. *Id.* Petitioners fail to address any of the responses EPA provided to this study.

With respect to the case studies submitted, EPA explained that commenters did not provide sufficient information to meaningfully compare the costs in these case studies with EPA's peer-reviewed cost models. JA-[RTC_13-217]. For example, the report provided only minimal information about the systems involved and did not state which cost figures were estimates versus as-built costs; whether all of the case study costs were directly associated with PFAS treatment as opposed to other improvements; or whether the design parameters would be similar to the values used in EPA's models. *Id.*

And regarding possible increases in cost related to higher demand, Utility Br. 54, EPA responded that treatment costs are unlikely to significantly increase as a result of compliance with the Rule. JA-[RTC_13-117]. EPA explained that the Rule's two-year compliance extension, together with the availability of multiple available treatment technologies and non-treatment options for compliance, were expected to alleviate price pressure on treatment systems. *Id.*

Second, Petitioners suggest that EPA underestimated the number of systems that would be impacted by the Rule by relying solely on sampling data from the UCMR3 program, in which the reporting thresholds for PFAS were higher than the Rule's Standards. Industry Br. 19-20. But this argument is misplaced because EPA's occurrence estimates did not simply rely on UCMR3 data alone. Rather, EPA used data from UCMR3 to inform a statistically robust, peer-reviewed occurrence model, together with more recently collected data from state datasets using lower reporting thresholds. JA-[FR_32597-98]. EPA's use of this model allowed it to generate reasonable estimates of occurrence for the PFAS contaminants regulated in this Rule, including at levels below the UCMR3 reporting thresholds. *Id.*

Moreover, the preliminary results available from UCMR5 did not undermine EPA's occurrence estimates. EPA was not "obligated to use" its preliminary data gathered pursuant to UCMR5, Industry Br. 20, because that data did not represent the "best *available* public health information," JA-[FR_32601]. Indeed, the UCMR5 data was not actually "available" for use in the rulemaking at all. At the time of the Rule's promulgation, EPA had only received approximately 24 percent of the total data expected to be submitted under UCMR5, with the participating systems having varying degrees of completeness in their sample collection. *Id.*

While this preliminary data did not form the basis of this rulemaking, EPA did consider the results it had received, which confirmed EPA's conclusions based on the extensive UCMR3 and state data utilized in its occurrence modeling analyses. *Id.* The preliminary results did not suggest that EPA underestimated the number of systems that would incur compliance costs. *Contra* Industry Br. 20. While the preliminary results showed that 15.8 percent of systems reported at least one sample above the level of the Standards, these results do not represent *exceedances* of the Standards, since compliance is determined based on a running annual average. JA-[FR_32601]. Although the preliminary UCMR5 data was insufficient to actually calculate such averages, EPA observed that 9.4 percent of systems reported mean concentrations above the level of the Standards, consistent with the 6.2-10.1 percent range predicted by EPA's occurrence model. JA-[FR_32602, 32605]. And even this figure likely overestimates occurrence, since the UCMR5 results overrepresent large systems. *See* JA-[FR_32605] (estimating only 7.8 percent of systems would have mean concentrations exceeding a Standard after weighting for system size).

Third, Petitioners argue that EPA failed to account for the costs of treating HFPO-DA, PFNA, and PFBS to comply with the Standards. Industry Br. 18-19. But far from omitting these costs, EPA went out of its way to account for them in its Economic Analysis. EPA explained that it lacked sufficient nationally

representative data to precisely estimate the occurrence of these three contaminants and, thus, to estimate the number of systems that would incur costs to comply with the Standards applicable to them. *See* JA-[FR_32533]. Nevertheless, EPA accounted for the costs of treating HFPO-DA, PFNA, and PFBS as nonquantifiable costs in its Economic Analysis, as required by Section 300g-1(b)(3)(C)(i)(III). JA-[FR_32671-72]. And to better understand the potential impact of these costs, EPA performed a quantitative sensitivity analysis to estimate the impact that treating these contaminants might have on the Rule's overall costs. JA-[FR_32533]; JA-[Economic_Analysis_App'x_EPA-HQ-OW-2022-0114-3085_N.3-N.4]. This sensitivity analysis indicated that the costs of treating these contaminants would likely increase the national cost impacts by $82.4 million, or approximately 5 percent of the Rule's overall quantified costs. JA-[FR_32672].

Petitioners appear to believe that EPA cannot possibly have considered these costs because if it had, EPA would have had to reject the Standards applicable to these contaminants as unjustified. But Petitioners yet again fail to consider the significant nonquantifiable benefits associated with reductions in HFPO-DA, PFNA, and PFBS, which SDWA requires EPA to account for in its Economic Analysis. *See* JA-[FR_32700] (summarizing nonquantifiable benefits).

V. None of Petitioners' Arguments Warrant Vacatur of the Entire Rule.

Setting aside the substantive and procedural defects in Petitioners' arguments, the relief they request—vacatur of the Rule in its entirety—far exceeds the scope of any argument they present. Utility Br. 57; Industry Br. 60. In the event that the Court concludes any of Petitioners' arguments have merit, any relief should be limited to the specific provisions of the Rule for which the Court finds error.

EPA finalized several distinct actions in this Rule, including: a regulatory determination for mixtures of Index PFAS; individual regulatory determinations for three of those Index PFAS (PFHxS, PFNA, and HFPO-DA); Goals for PFOS, PFOA, PFHxS, PFNA, HFPO-DA, and mixtures of the Index PFAS; and Standards for those same contaminants. JA-[FR_32532]. EPA's actions for each contaminant are independent of one another and can be implemented on their own. JA-[FR_32731-32]. Accordingly, a finding that EPA erred in addressing one of these contaminants cannot support vacatur of EPA's actions for the other contaminants. Likewise, EPA's actions at the various steps of the regulatory process are severable. For example, a finding that EPA erred in setting the Standard for a contaminant (*e.g.*, by selecting a level that is not feasible) cannot justify vacatur of the Goal or the regulatory determination for that contaminant. JA-[FR_31732].

Each of Petitioners' arguments focuses on individual provisions of the Rule; nowhere in their briefs do Petitioners raise any global issue that might affect the validity of the Rule as a whole. Indeed, no Petitioner has articulated any challenge to EPA's regulatory determinations for PFOS and PFOA or its Goals for those contaminants. Thus, Petitioners cannot justify vacatur of the entire Rule.

Petitioners' arguments regarding the Rule's analysis of costs and benefits are no exception. *See* Industry Br. 15. Even if the Court finds EPA's Economic Analysis was arbitrary and capricious, any error in that analysis cannot possibly justify vacatur of those portions of the Rule that, under the statutory text, are not based on consideration of cost. In particular, because the Economic Analysis under Section 300g-1(b)(3)(C) plays no role in the regulatory determination or the Goal for a contaminant, any defects in that analysis would not provide grounds for the Court to vacate *those* portions of the Rule. *See* 42 U.S.C. § 300g-1(b)(1).

And in any event, even where the benefits of a Standard set at the feasible level do not justify its costs, the Act grants EPA *discretionary* authority either to promulgate a less stringent alternative Standard or proceed with setting a Standard at the feasible level. *Id.* § 300g-1(b)(6). Thus, on remand from a decision of this Court reversing EPA's determination that the Rule's benefits justify its costs, EPA could simply decide in its discretion to retain some or all of the Rule's Standards at their current levels. Given that reasonable possibility, it would be unnecessarily

disruptive to vacate those Standards in the interim. *See Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993).

CONCLUSION

The Court should deny the petitions for review.

Respectfully submitted,

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CERTIFICATES OF COMPLIANCE AND SERVICE

I certify that this document complies with Fed. R. App. P. 32(a)(5) and (6) because it uses 14-point Times New Roman, a proportionally spaced font, with 1-inch margins.

I also certify that this document complies with Fed. R. App. P. 32(a)(7)(B)(i) and the Court's Briefing Order (ECF No. 2072754) because according to Microsoft Word's count, it has 25,699 words, excluding the parts of exempted under Fed. R. App. P. 32(f) and D.C. Cir. R. 32(e)(1).

Finally, I certify that on December 23, 2024, I electronically filed this document with the Court's CM/ECF system, which will serve each party's counsel of record.

_/s/ Kimere J. Kimball_____
KIMERE J. KIMBALL